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**(54) CLOSED FLUID TRANSFER SYSTEM**

GESCHLOSSENES FLÜSSIGKEITSTRANSFERSYSTEM

SYSTÈME DE TRANSFERT DE FLUIDE FERMÉ

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## Description

### BACKGROUND

#### 1. Technical Field

**[0001]** The present disclosure relates generally to closed fluid transfer systems and their related components, and more particularly, to components and systems for the transfer of gases/liquids/fluid or other substances from a first container to a second container while maintaining a closed system.

#### 2. Background of Related Art

**[0002]** In one instance, hazardous medicines are frequently applied in the treatment of certain diseases, in particular, for example, in the treatment of cancer. Cytotoxic drugs have generally been used to kill cancer cells. However, the use of cytotoxic drugs, in the treatment of cancer cells, presents specific dangers to all cells, both in the patient and in healthcare providers. Although the exposure to a health care provider is normally very small for each cytotoxic drug dose administration, evidence suggests that chronic, low-dose exposure can produce significant health problems. Accordingly, a system that allows the safe handling of hazardous drugs while significantly reducing and/or eliminating the exposure to providers would be of great benefit.

**[0003]** Drugs are typically supplied in glass or plastic vials that are capped with a gas impermeable liquid seal or stopper. In some instances, the vial contents are a solid powder, such that a liquid needs to be injected for mixing (e.g., reconstitution). The injection of additional contents (e.g., liquid) into the vial produces an increased pressure which stresses the seal or stopper. Although the vial is intended to be sealed to liquid and gases, drug molecules in vapor phase can leak or pass around the sides of the stopper or through the stopper as the injection needle is withdrawn, thus presenting a hazard to the provider or clinician.

**[0004]** Accordingly, with the potential for aerosol leakage, leakage/spraying upon needle withdrawal, or spills, a means with which to prevent the accidental vapor phase drug egress is required.

**[0005]** Thus, the need exists for new components and systems capable of transferring gases/fluids/liquids or other substances between a conventional syringe and one of a vial, a patient I.V. (intra-venous) set, or an I.V. bag without leaking or spilling and without exposure of the liquids to substances outside the closed system. As such, healthcare personnel may more safely use and handle fluid substances including potentially hazardous liquids and the like.

### SUMMARY

**[0006]** The present disclosure relates to components

and systems for the transfer of a fluid/substance from a first container to a second container while maintaining a closed system.

**[0007]** It is known from US2008/142388 to provide a vial adapter for a closed fluid transfer system. The vial adapter includes a base defining an opening having a plurality of retainers extending around the opening of the base and being configured to snap-fit connect to a neck of a vial.

**[0008]** The vial adapter according to the present invention as defined by the appended claims is characterized in that the base defines a lower inner annular rim and an outer annular rim and a cavity therebetween; the vial adapter further including a cover supported on the outer rim of the base, wherein an expansion chamber is defined within the cover and the base; and an adapter support situated within the cavity of the base. The adapter support includes an annular flange for seating on the lower inner annular rim of the base and forming a fluid tight seal therebetween; an annular wall extending from the annular flange and defining an upper inner annular rim, wherein the cover is also supported on the upper inner annular rim; a male stem extending in a first direction from the annular flange; a male stem for selectively connecting to and insertion into a open distal end of a syringe adapter, the male stem defining a lumen extending therethrough; a pair of opposed guide pins extending radially outward from the male stem; a pair of opposed guide surfaces extending radially outward from the male stem at a location proximal of the guide pins and being in registration with the guide pins; a seal extending across the lumen of the male stem; and a spike extending in a second direction from the annular flange, wherein the spike extends into the opening of the base, wherein the spike includes a first lumen being in fluid communication with the lumen of the male stem, and wherein the spike includes a second lumen being in fluid communication with the expansion chamber. The vial adapter further includes a bladder extending between the inner upper annular rim and the outer annular rim of the base.

**[0009]** Also according to the invention there is provided a vial adapter and a syringe adapter. The vial adapter is configured to move the syringe adapter from a closed state to an open state. The syringe adapter includes a housing defining an open distal end and an open proximal end, the housing defining a pair of opposed longitudinally extending slots opening from the open distal end of the housing, the housing including a pair of opposed longitudinally extending ribs projecting from an inner surface thereof; a base supported in the open proximal end of the housing and including a syringe adapter luer connector; a collar slidably and rotatably supported in the housing, the collar defining a longitudinal opening there-through, the collar defining a pair of opposed L-shaped tracks formed in an outer surface thereof and configured to receive a respective longitudinally extending rib therein, the collar defines a pair of opposed helical tracks opening from a distal surface of the collar, the opposed helical

tracks being aligned with a respective slot of the housing when the collar is in a distal-most position; a shuttle slidably extending through longitudinal opening of the collar, the shuttle defining a shuttle lumen extending longitudinally therethrough; a barrel supported on and extending over a distal end of the shuttle, the barrel defining a central opening aligned with the shuttle lumen; and a biasing member interposed between the collar and the shuttle for urging the collar away from the shuttle; a syringe first adapter seal is interposed between the shuttle and the barrel, wherein the syringe first adapter seal extends across the shuttle lumen and the central opening of the barrel; and a needle (27) defining a lumen (67) therethrough, the needle (27) having a proximal end supported in the base (47) such that the lumen (67) of the needle (27) is in fluid communication with the luer connector (69), the needle (27) having a sharpened distal tip (61) disposed within the lumen (81) of the shuttle (29) when the shuttle (29) is in a distal-most position.

**[0010]** In use, the vial adapter moves the syringe adapter from the closed state to the open state upon inserting the guide pins of the male stem of the vial adapter into the respective slots of the housing of the syringe adapter, whereby the seal of the vial adapter abuts the seal of the syringe adapter; advancing the male stem of the vial adapter into the open distal end of the housing such that the guide pins enter into the respective helical track of the collar to (1) rotate the collar relative to the housing of the syringe adapter and (2) align the ribs of the housing with a through portion of the collar; and further advancing the male stem of the vial adapter into the open distal end of the housing causing the collar to move proximally which causes the shuttle to move proximally until the tip of the needle penetrates through the abutting seals, whereby the syringe adapter is in the open state and fluidly interconnects the syringe with the vial adapter.

**[0011]** The spike of the vial adapter may penetrate a septum of the vial upon a connection of the base of the vial adapter to a neck of the vial.

**[0012]** When the syringe is connected to the syringe adapter, and when the syringe adapter is connected to the vial adapter, and when the vial adapter is connected to the vial, the syringe is in closed fluid communication with the vial.

**[0013]** When the syringe is connected to the syringe adapter, and when the syringe adapter is connected to the vial adapter, the tip of the needle of the syringe adapter penetrates the abutting seals of the syringe adapter and the vial adapter and when the vial adapter is connected to the vial, the syringe is in closed fluid communication with the vial.

**[0014]** In use, air from the syringe may be injectable into a cavity of the vial adapter defined between the bladder, and the base and the adapter support, through a fluid passage defined by the needle of the syringe adapter, the lumen of the male stem, the first lumen of the spike, the vial and the second lumen of the spike.

**[0015]** The invention will be explained in greater detail

below in descriptions of preferred embodiments and referring to the attached figures.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0016]** In the following, the preferred embodiments of invention will be described in detail with reference to the following attached figures:

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FIG. 1 is a schematic illustration of a closed fluid transfer system of the present disclosure illustrating a fluid connectability of a syringe to an I.V. set, a vial and an I.V. bag via combination of a syringe adapter and one of an I.V. set adapter, a vial adapter and an I.V. bag adapter;

FIG. 2 is a perspective view of a syringe adapter of the closed fluid transfer system of FIG. 1;

FIG. 3 is a perspective view, with parts separated, of the syringe adapter of FIG. 2;

FIG. 4 is a longitudinal, cross-sectional view of the syringe adapter of FIGS. 2 and 3;

FIG. 5 is an enlarged view, of the indicated area of detail of FIG. 2, with the outer side portions shown in phantom;

FIG. 6 is a top, perspective view of a collar of the syringe adapter of FIGS. 1-5;

FIG. 7 is a longitudinal cross-sectional view of the collar of FIGS. 5 and 6;

FIG. 8 is a perspective view of a vial adapter of the closed fluid transfer system of FIG. 1;

FIG. 9 is a perspective view, with parts separated, of the vial adapter of FIG. 8;

FIG. 10 is a longitudinal, cross-sectional view of the vial adapter of FIGS. 8 and 9;

FIG. 11 is a top, perspective view of a patient push adapter of the closed fluid transfer system of FIG. 1;

FIG. 12 is a bottom, perspective view of a patient push adapter of the closed fluid transfer system of FIG. 1;

FIG. 13, is a perspective view, with parts separated, of the patient push adapter of FIGS. 11 and 12;

FIG. 14 is a longitudinal, cross-sectional view of the patient push adapter of FIGS. 11-13;

FIG. 15 is a bottom, perspective view of an I.V. bag

adapter of the closed fluid transfer system of FIG. 1;

FIG. 16 is a longitudinal, cross-sectional view of the I.V. bag adapter of FIG. 15;

FIG. 17 is a distal, perspective view of a syringe adapter, with the housing removed, according to another embodiment of the present disclosure;

FIG. 18 is a side, elevational view of a distal end of the syringe adapter of FIG. 17, with one housing half removed;

FIG. 19 is a further side, elevational view of a distal end of the syringe adapter of FIG. 17;

FIG. 20 is a longitudinal, cross-sectional view of a distal end of the syringe adapter of FIGS. 17-19;

FIG. 21 is a further, longitudinal, cross-sectional view of a distal end of the syringe adapter of FIGS. 17-19, illustrating a locking system of the syringe adapter in a first condition;

FIG. 22 is a cross-sectional view of the syringe adapter of FIG. 21, as taken through 22-22 of FIG. 21;

FIG. 23 is a further, longitudinal, cross-sectional view of a distal end of the syringe adapter of FIGS. 17-19, illustrating a locking system of the syringe adapter in a second condition;

FIG. 24 is a cross-sectional view of the syringe adapter of FIG. 23, as taken through 24-24 of FIG. 22;

FIG. 25 is a schematic, elevational view of a universal vial adapter according to an embodiment of the present disclosure, shown connected to a vial neck having a first diameter;

FIG. 26 is a top, plan view of a hub of the universal vial adapter as connected to the vial of FIG. 25;

FIG. 27 is a perspective view of the hub of the universal vial adapter as connected to the vial of FIG. 25;

FIG. 28 is a schematic, elevational view of the universal vial adapter of FIG. 25, shown connected to a vial neck having a second diameter;

FIG. 29 is a top, plan view of a hub of the universal vial adapter as connected to the vial of FIG. 28;

FIG. 30 is a perspective view of the hub of the universal vial adapter as connected to the vial of FIG. 28;

FIG. 31 is a schematic, longitudinal, cross-sectional view of the universal vial adapter of FIGS. 25-30; and

FIGS. 32-38 illustrate a sequence of fluidly connecting a syringe adapter and a patient push adapter.

#### DETAILED DESCRIPTION

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**[0017]** The closed fluid transfer system, in accordance with the present disclosure, is generally designated as 100 and generally includes a module/adapter that fluidly connects to a syringe or any male luer lock connection point; a patient push module/adapter that fluidly connects directly to an I.V. line; at least a module/adapter that fluidly connects to a vial/container storing/containing a fluid/liquid in the form of a hazardous drug and the like; and a module/adapter that fluidly connects to an I.V. bag. Each of the above-mentioned modules/adapters will be described in greater detail below with reference to the accompanying figures, wherein like numbers identify like elements.

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**[0018]** In accordance with the present disclosure, the system is a "closed" fluid-transfer system capable of transferring liquids between a conventional syringe and one of a patient I.V. set, a vial, or an I.V. bag without leaking or spilling and without exposure of the gases/fluids/liquids or other substances to a location or a substance outside the closed system. One purpose of the closed fluid transfer system is to permit health care personnel to safely use and handle liquid-form medicine, including potentially hazardous liquid drugs and/or the like.

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**[0019]** In accordance with the present disclosure, and as will be discussed in greater detail below, the closed fluid transfer system 100 includes a syringe adapter 11 (see FIGS. 1-7) that is structured to provide a closed fluid connection between a first fluid container in the form of a conventional needleless syringe "I" and a second fluid container/conduit in the form of a patient I.V. set, a vial "V", or an I.V. bag. The fluid transfer is accomplished by first connecting one of a patient push adapter 15 (see FIGS. 1 and 11-14) to an I.V. set, a vial adapter 13 (see FIGS. 1 and 8-10) to a vial, or an I.V. bag adapter 17 (see FIGS. 1 and 15-16) to an I.V. bag, as necessary. Each adapter 13, 15, 17 is provided with an identical male stem 19 which defines an internal lumen 21 closed at one end by a resilient seal 23. The syringe adapter 11 is mated to the male stem 19, thereby permitting fluid flow from or to the syringe "I", as described in more detail herein.

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**[0020]** Referring now specifically to FIGS. 1-7, the closed fluid transfer system 100 includes a syringe adapter 11. Syringe adapter 11 is a type of valve which can be in an open state to permit fluid flow therethrough or in a closed state to prevent fluid flow. The open and closed states occur in a specific sequence dictated by the syringe adapter 11 architecture as described herein.

**[0021]** The syringe adapter 11 consists of four main parts which are a housing 25, a conventional hollow metal needle 27, a shuttle 29, and a collar 31. The housing 25 is generally cylindrical in shape having a distal end 33

and a proximal end 35, a longitudinal axis 37, a distal opening 39, and a female cavity 41 into which the male stem 19 is received. Housing 25 may be formed to have two housing side portions or halves 43, 45 and a housing base portion 47 which fits partially between the side portions 43, 45. Side portions 43, 45 define opposed slots 49, 51 (see FIGS. 2 and 4) which begin at housing distal end 33 and extend within housing 25. Slots 49, 51 which receive a respective guide pin 53, 55 and guide surface 57, 59 of any male stem 19, which are each keyed to a respective one of the slots 49, 51 (or a respective one of slots 51, 49), for the purposes described in full detail below.

**[0022]** Hollow metal needle 27, as seen in FIGS. 3 and 4, is a conventional needle with a sharpened tip 61, a tip end opening 63, a proximal end opening 65, and a lumen 67 permitting fluid flow through the conventional needle 27 between the needle openings 63, 65. It is envisioned that needle 27 will be a conventional 18 gauge steel "pencil tip" needle commercially available (18 gauge refers to the outer diameter of needle 27). The conventional pencil tip needle 27 has an extremely sharp tip 61 with opening 63 spaced slightly away from the sharpened tip 61. The pencil tip needle 27 is of a type and size conventionally used with syringes to penetrate patient blood vessels for delivery or extraction of fluids.

**[0023]** Needle 27 is mounted within housing 25, in fixed-positional relationship, on an inner side of base 47 with tip 61 of needle 27 pointing/extending toward distal end 33 of housing 25. An advantage of this design is that needle 27, and specifically, the extremely sharp needle tip 61 of needle 27, are fully enclosed within the housing 25 and are completely shielded from contact with a user. In this manner, the possibility of injuries as a result of user needle-stick, has been significantly reduced and/or eliminated.

**[0024]** Housing base 47 is rotatably supported in housing 25. Housing base 47 includes an outer side with a conventional luer connector 69 provided to accept the delivery end of a conventional needled syringe. A lumen 71 extends through base 47 between luer connector 69 and proximal opening 65 of needle 27 permitting fluid flow between the needle tip opening 63 and the luer connector 69.

**[0025]** Housing 25 and housing base 47 of syringe adapter 11 cooperate with one another to provide a ratchet mechanism by which syringe adapter 11 may not be accidentally or inadvertently disconnected from syringe "I". In particular, the ratchet mechanism includes, as seen in FIG. 3, a plurality of ribs 25a formed on an inner surface of housing 25 and at least one resilient finger 47a supported on housing base 47, whereby housing base 47 is held in a fixed position relative to housing 25 when syringe adapter 11 is connected to syringe 11 and to is free to rotate relative to housing 25 if syringe adapter 11 is being inadvertently or accidentally disconnected from syringe "I". In this manner, the closed system between the syringe adapter 11 and syringe 11 is better maintained.

**[0026]** Generally, in operation, when syringe adapter 11 is connected to syringe "I", the at least one resilient finger 47a of housing base 47 engages ribs 25a of housing in such a manner that rotation of housing base 47 relative to housing 25 is inhibited and syringe adapter 11 may be securely connected to syringe "I". Further, if there is an inadvertent or accidental rotation of syringe adapter 11 relative to syringe "I", tending to disconnect syringe adapter 11 from syringe "I", and thus destroy the closed system, each resilient finger 47a is configured to slip over and across ribs 25a of housing 25, allowing housing base 47 to rotate relative to housing 25 and thus maintain the closed system.

**[0027]** If it is desired to intentionally disconnect syringe "I" from syringe adapter 11, a user may squeeze housing 25 radially inward, in the proximity of luer connector 69, to engage at least one tooth (not shown) formed on an inner surface of housing 25 with a respective notch 47b formed in an outer surface of housing base 47. Then, with the at least one tooth (not shown) of housing 25 engaged with the respective notch 47b of housing base 47, the user may rotate syringe adapter 11 relative to syringe "I" to disconnect syringe "I" from luer connector 69 of housing base 47.

**[0028]** Shuttle 29 is provided for at least the following important purposes. First, shuttle 29 supports shuttle distal seal 73 across distal opening 39 of housing 25 to close cavity 41 of housing 25 so that contaminants cannot enter the housing 25 when the syringe adapter 11 is not mated to one of the adapters 13, 15, 17. Second, the shuttle 29 supports shuttle distal seal 73 at a position across distal opening 39 of housing 25 so that distal seal 73 can be easily swabbed with alcohol before use to ensure that the seal 73 is sterile. In accordance with the present disclosure, and as is customary, a seal 23 of any male stem 19 (as seen in for example FIG. 8 and as will be described in greater detail below) is also swabbed with alcohol or other microbial agent before being mated to the syringe adapter 11, so as to ensure sterility of the abutment between seals 23 and 73. Finally, the shuttle 29 provides a fluid-tight enclosure for needle 27 to prevent fluid flow outside of syringe adapter 11 when in the closed state.

**[0029]** As illustrated in FIGS. 3 and 4, shuttle 29 includes distal and proximal annular flanges 75, 77, respectively, and an intermediate body portion 79 between flanges 75, 77 defining a shuttle lumen 81 therethrough. Distal flange 75 supports a distal seal 73 and a barrel 83, seated on distal flange 75, holds distal seal 73 on distal flange 75. Shuttle proximal flange 77 supports a proximal seal 85.

**[0030]** As illustrated in FIGS. 3 and 4, tip 61 of needle 27 extends into shuttle lumen 81 and proximal seal 85 forms a fluid-tight seal around needle 27. In the closed state, when syringe adapter 11 is fluidly connected to syringe "I", needle tip 61 and opening 63 are within shuttle lumen 81 and seals 73, 85 prevent fluid from exiting shuttle lumen 81.

**[0031]** Each seal 23, 73 is generally disk shaped and

includes a respective outward projection 87, 89 (i.e., convex surface) which abut one another when the seals 23, 73 are held together, as described later herein. Seals 23, 73 and 85 are made of polyisoprene and seals 23 and 73 are designed want to retain or return to their original convex profile when in abutment with one another. Put another way, since seals 23, 73 are fabricated from a resilient material and tend to want to retain or return to their original convex profile, when seals 23, 73 are in abutment with one another, a substantially continuous interface between seals 23, 73 is established and maintained. While it is preferred that seals 23 and 73 be made from polyisoprene, it is contemplated and within the scope of the present disclosure, that seals 23, 73 may be made from thermoplastic elastomers (TPE), silicone, more specifically, HaloButyl-Polyisoprene, Chlorobutyl, thermoplastic vulcanizates (TPVs), any other resilient polymer, or any combinations thereof.

**[0032]** Intermediate portion 79 of shuttle 29 rides in collar opening 91 in collar end wall 93 of collar 31 for axial movement along axis 37 within housing 25. Barrel 83 is generally cylindrical in shape and has an outside diameter slightly less than an inside diameter of collar 31 to permit barrel 83 and shuttle 29 to reciprocate inside collar 31.

**[0033]** A spring 95 is provided and bears against end wall 93 of collar 31 and distal flange 75, partially within barrel 83. Spring 95 biases shuttle 29 toward distal end 33 of housing 25 so that distal seal 73 of shuttle 29 covers or extends across opening 39 of housing 25, for the reasons previously described. Spring-biased contact between barrel 83 and end wall 93 of collar 31 limits inward movement of shuttle 29 toward proximal end 35 of housing 25, and contact between proximal flange 77 of shuttle 29 and end wall 93 of collar 31 limits outward movement of shuttle 29 toward distal end 33 of housing 25.

**[0034]** Distal seal 73 of shuttle 29 does not contact the housing 25 and is supported solely by shuttle 29 and travels within collar 31 spaced from housing 25. Shuttle 29 is pushed axially toward proximal end 35 of housing 25 when contacted by seal 23 of any male stem 19 during use, as described more fully below.

**[0035]** With continued reference to FIGS. 2-7, collar 31 and housing 25 cooperate to hold male stem 19 and seal 23 (for example, as seen in FIG. 8) thereof in abutment with distal seal 73 of shuttle 29 so that the abutting seals 23, 73 can subsequently be pierced by needle tip 61 of needle 27 and so that needle 27 can enter lumen 21 of male stem 19 to open the fluid path through syringe adapter 11. The abutment between seals 23, 73 established that distal seal 73 of shuttle 29 is the closure for distal opening 39 of housing 25 and also places distal seal 73 of shuttle 29 in a position convenient for swabbing with alcohol before use. The abutment between seals 23, 73 ensures that the two seals 23, 73 function as one and can be pierced together by needle 27. If the seals 23, 73 were to separate with needle tip opening 63 extended outside of lumen 81 of shuttle 29, liquids could

leak into cavity 41 of housing 25, which is contrary to the purpose of providing a closed system.

**[0036]** Referring now to FIGS. 3-7, collar 31 is generally cylindrical in shape corresponding to the shape of cavity 41 of housing 25. Collar 31 includes a proximal end wall 93 and a side wall 97 extending from proximal wall 93. Side wall 97 of collar 31 includes two opposed exaggerated angled L-shaped tracks 99 formed in an outer surface thereof, one of which can be seen in FIGS. 6 and 7. The other L-shaped track is not shown but is a mirror image of L-shaped track 99 shown. For simplicity, reference numeral 99 will refer to both L-shaped tracks. As seen in FIG. 6, each track 99 has a lower portion 101 defined by an upper stop wall or shoulder 103 and first and second lateral, longitudinally extending side walls 105, 107. Each track 99 further has a through portion 109 defined by second side wall 107 and a third side wall 111 which is on an end of upper stop wall 103.

**[0037]** On the inside surface of housing 25, facing collar 31 and projecting into each of the two L-shaped tracks 99, are two opposed longitudinally extending male ribs 113, one of which 113 can be seen in FIG. 5. The other rib is not visible but is a mirror image of visible rib 113. For simplicity reference number 113 will refer to both ribs. Each of the two ribs 113 is parallel relative to axis 37. Each rib 113 has a width which is slightly less than the gap between the second side wall 107 and the third side wall 111 defining the through portion 109.

**[0038]** In operation, each rib 113 cooperates with a respective L-shaped track 99 in an identical manner to permit limited rotational and axial movement of collar 31, as described herein. Specifically, contact between each rib 113 and respective first side wall 105 and second side wall 107, with respective upper stop wall 103 riding along rib 113, limits the rotational movement of collar 31 to about 6°, while collar 31 is constrained to move axially along axis 37. In this position, collar 31 supports distal seal 73 of shuttle 29 across opening 39 of housing 25.

**[0039]** After approximately 6° of rotational movement of collar 31, each rib 113 enters respective through portions 109 of L-shaped tracks 99, wherein contact between each rib 113 and respective second side wall and third side wall 107, 111 permits collar 31 to move axially along axis 37, but constrains collar 31 from further rotational movement. With each rib 113 in respective through portions 109, collar 31 can move axially along axis 37 toward proximal end 35 of housing 25 so that tip 61 of needle 27 can pierce abutting seals 23, 73 to place the syringe adapter 11 in an open state. Alternatively, collar 31 can move axially toward distal end 33 of housing 25 so that tip 61 of needle 27 exits seals 23, 73 and re-enters lumen 81 of shuttle 29 to place syringe adapter 11 in the closed state.

**[0040]** Side wall 97 of collar 31 further includes helical tracks 115, 117 formed in an outer surface thereof. Guide pins 53, 55 of any male stem 19 are received in a respective helical track 115 or 117 for purposes of rotating collar 31 and holding seals 23, 73 in abutment with one another,

as will now be described.

**[0041]** With reference to FIGS. 32-38, syringe adapter 11 (or syringe adapter 611, see FIGS. 17-24) operates in substantially a two-step manner. Initially, a male stem 19 supporting a seal 23, such as in the vial adapter 13 (not shown), the patient push adapter 15 (as shown in FIGS. 32-38) or the I.V. bag adapter 17 (not shown), is held in abutment with distal seal 73 of shuttle 29. Then, the held-together or abutting seals 23, 73 are pierced with the tip 61 of needle 27 so that needle 27 can enter the lumen 21 of male stem 19 to open the fluid path through syringe adapter 11, thereby placing syringe adapter 11 in the open state and in fluid communication with the vial adapter 13, the patient push adapter 15 or the I.V. bag adapter 17.

**[0042]** More specifically, in the initial step, as seen in FIGS. 32-34, diametrically opposed, radially extending guide pins 53, 55 of male stem 19 (of, for example, patient push adapter 15) and diametrically opposed, radially extending guide surfaces 57, 59 of male stem 19 are first inserted into respective slots 49, 51 of housing 25 with stem seal 23 of male stem 19 in abutment with distal seal 73 of shuttle 29. Next, stem seal 23 of male stem 19 enters cavity 41 (see FIGS. 4, 38) of housing 25 and guide pins 53, 55 of male stem 19 enter a respective helical track 115, 117 (or 715, 717) of collar 31 (or 631). Simultaneously, shuttle 29 moves axially along axis 37 toward end wall 93 of collar 31 (or 631) and proximal end 35 of housing 25, against spring 95 because collar 31 (or 631) is axially constrained by contact between each rib 113 (or 713) and a respective upper stop or side wall 103 of collar 31 (or 631). Due to the axial constraint imposed on collar 31 (or 631) by each rib 113 (or 713) and respective upper side walls 103, shuttle 29 will move axially toward proximal end 35 of housing 25 until barrel 83 of shuttle 29 bottoms out against end wall 93 of collar 31 (or 631).

**[0043]** Axial movement of guide pins 53, 55 of male stem 19, within a respective collar helical track 115, 117 (or 715, 717), while collar 31 (or 631) is axially constrained, causes collar 31 (or 631) to rotate (counterclockwise as illustrated in the FIGS. 36 and 37) and each of the two upper side walls 103 of collar 31 (or 631) to slide along a respective rib 113 (or 713). As mentioned above, this rotation of collar 31 (or 631) is limited to about 6° by contact between ribs 113 (or 713) and a respective second side wall 107. Male stem 19 is unable to rotate as male stem 19 is inserted into syringe adapter 11 (or 611) because guide surfaces 57, 59 of male stem 19 are constrained within slots 49 and 51 of housing 25.

**[0044]** The restraint on further rotation of collar 31 (or 631), provided by contact between the ribs 113 (or 713) and the respective second side walls 107, in turn, limits further axial movement of male stem 19 because the guide pins 53, 55 of male stem 19 are now axially constrained by the helical tracks 115, 117 (or 715, 717) of collar 31 (or 631). When shuttle 29 is bottomed out against end wall 93 of collar 31 (or 631), further axial

movement of shuttle 29 relative to collar 31 (or 631) is prevented. The result is that seal 23 of male stem 19 is held in abutment against distal end seal 73 of shuttle 29. Tip 61 of needle 27 remains axially spaced from abutting seals 23, 73 and there is no fluid flow through syringe adapter 11 (or 611).

**[0045]** In the following step, as seen in FIG. 38, the user pushes male stem 19 and abutting seals 23, 73 further into cavity 41 of housing 25 (see FIGS. 4, 38) of syringe adapter 11 (or 611). Further axial movement of shuttle 29 and collar 31 is possible now because collar 31 has been rotated so that through portion 109 of each collar L-shaped track 99 (see FIGS. 5-7) is in alignment with a rib 113 (or 713), wherein ribs 113 (or 713) are between second and third side walls 107, 111 (see FIGS. 5-7). Further movement of male stem 19 into cavity 41 (see FIG. 4) moves collar 31 (or 631) and abutting seals 23, 73 toward tip 61 of needle 27 causing tip 61 of needle 27 to pierce the abutting seals 23, 73 and further causing needle 27 to enter lumen 21 of male stem 19 to open the fluid path through syringe adapter 11 (or 611), thereby placing syringe adapter 11 (or 611) in the open state and in fluid communication with the vial adapter 13 (not shown), the patient push adapter 15 or the I.V. bag adapter 17 (not shown). Fluids can now flow from needle 27 toward the vial adapter 13, the patient push adapter 15 or the I.V. bag adapter 17, or can flow in a reverse direction.

**[0046]** To remove the male stem 19 of the vial adapter 13 (not shown), the patient push adapter 15 or the I.V. bag adapter 17 (not shown) from syringe adapter 11 (or 611), the adapter 13, 15, or 17 is pulled fully away from the distal end 33 of housing 25. The process described above takes place in reverse, thereby stopping a flow of fluid once needle tip 61 is fully retracted within lumen 81 of shuttle 29 (see FIG. 4), thereby placing the syringe adapter 11 (or 611) into the closed state.

**[0047]** In accordance with the present disclosure, as seen in FIGS. 2-5, it is further contemplated that distal end 33 of housing 25 of syringe adapter 11 may have a substantially sinusoidal distal profile or distal end surface 33a (see FIG. 2), wherein opposed slots 49, 51 of syringe adapter 11 are disposed at a respective opposed nadir or low point of distal end surface 33a. Meanwhile, as seen in FIGS. 11-13, body 301 of patient push adapter 15 may include a substantially sinusoidal profile or surface 301a extending therearound, wherein opposed guide surfaces 55, 57 of patient push adapter 15 are disposed and a respective opposed apex or high point of surface 301a. It is contemplated that distal end surface 33a of syringe adapter 11 and surface 301a of patient push adapter 15 substantially complement one another.

**[0048]** Turning now to FIGS. 1 and 8-10, vial adapter 13 of the closed fluid transfer system 100 of the present disclosure, will be discussed in greater detail. Generally, vial adapter 13 connects to a neck "N" of a vial, bottle, or other container "V" holding liquid "L" to be extracted or into which liquid is to be delivered. For convenience,

these containers will be referred to collectively by the term "vial." Vial adapter 13 may be provided in sizes and configurations as necessary to attach to commercially-available vials.

**[0049]** As illustrated in FIGS. 8-10, vial adapter 13 includes a base 201, an adapter support 203 (including a male stem 19 supporting a seal 23 and including guide pins 53, 55, as described above), a spike 205, and an expansion chamber 207. Vial adapter 13 includes distal and proximal ends 209, 211.

**[0050]** As best shown in FIGS. 9 and 10, base 201 is substantially bowl-shaped and is configured to receive and/or seat an adapter support 203 thereon. Vial adapter 13 includes a toroid-shaped expansion chamber 207, including a bladder 227 and translucent cover 215, seated on an inner rim and an outer rim of base 201. Bladder 227 having a substantially U-shaped radial cross-section including a first annular rim captured between the outer annular rim of base 201 and the outer annular rim of cover 215, and a second annular rim captured between the inner annular rim of base 201 and the inner annular rim of cover 215.

**[0051]** Base 201 of vial adapter 13 includes a circular opening 217 along proximal end 211 thereof into which neck "N" of vial "V" is received. Retainers 219 are provided around the circumference of opening 217 to connect base 201 of vial adapter 13 to form a permanent connection once the neck "N" of the vial "V" is inserted into opening 217.

**[0052]** As seen in FIG. 10, spike 205 extends away from proximal end 211 of base 201 and includes a tip 221 configured to pierce a septum "S" provided on vial "V" when the neck "N" of the vial "V" is inserted into opening 217 of base 201. Spike 205 has a length sufficient to extend into the vial "V". Spike 205 is preferably made of plastic, however, it is envisioned that spike 205 may preferably support a metallic piercing member or hypo-tube 205a to assist in the ability of spike 205 to penetrate the septum "S" of the vial "V".

**[0053]** As seen in FIG. 10, spike 205 and adapter support 203 define two ducts 223, 225. A first duct 223 extends between tip 221 of spike 205 and lumen 21 of male stem 19, and is provided to permit fluid flow between the vial "V" and male stem 19. As described above, opening 63 of tip 61 of needle 27 extends into lumen 21 to extract or deliver liquid through duct 223 when syringe adapter 11 is in the open state. A second duct 225 extends between tip 221 of spike 205 and a first cavity 207a of chamber 207 defined within expansion chamber 207 when toroid-shaped bladder 227 is deflated. Chamber 207a of expansion chamber 207 expands upon a movement of bladder 227 when air or other gas is injected into male stem 19 and duct 223 from a syringe "I" that is attached to syringe adapter 11.

**[0054]** In operation, vial adapter 13 is initially connected to neck "N" of vial "V" with spike 205 piercing septum "S" of vial "V" such that ducts 223, 225 of spike 205 extend into the vial "V". Syringe adapter 11 (as shown and de-

scribed above) is then attached to male stem 19 of vial adapter 13, as described previously. Liquid "L" may then be extracted from or delivered to the vial "V". If the user wishes to first charge the syringe "I" with air or other gas, then the air may be transferred through the ducts 223, 225 of spike 205 of vial adapter 13 and into first cavity 207a of chamber 207, wherein bladder 227 is moved to accommodate the air. Air in first cavity 207a of chamber 207 moves back into the vial "V" as liquid "L" is withdrawn from the vial "V" and into the syringe "I".

**[0055]** The vial "V" and vial adapter 13 are discarded once the liquid "L" is removed from the vial "V".

**[0056]** It is contemplated and understood that proximal end 211 of base 201 may be sized to accommodate different size necks of different size vials, such as, for example, a 20mm vial cap of a 60ml vial; a 28mm vial cap of a 60ml vial; and a 13mm vial cap of a 20ml vial. Accordingly, a diameter of proximal end of base 201 of vial adapter 13 may be sized appropriately so as to accommodate at least the caps of the vials identified above.

**[0057]** It is contemplated that at least one nub (not shown) may project from a surface of respective guide surfaces 57, 59 of vial adapter 13 and which are configured to snap-fit engage respective complementary detents or recesses defined in slots 49, 51 of syringe adapter 11, or more particularly, an appropriately sized annular rib 49a (see FIG. 3) formed in an inner surface of halves 43, 45 of housing 21 of syringe adapter 11. The interaction of the nubs of the guide surfaces 57, 59 of vial adapter 13 and complementary detents or recesses defined in slots 49, 51 or annular rib 49a (see FIGS. 3 and 4) of syringe adapter 11 provide a user with audible and/or tactile feedback that vial adapter 13 and syringe adapter 11 are properly and fully connected to one another.

**[0058]** Turning now to FIGS. 1 and 11-14, patient push adapter 15 of the closed fluid transfer system 100 of the present disclosure, will be discussed in greater detail. In general, patient push adapter 15 connects to tubing of a patient I.V. set permitting delivery of liquids directly to the patient from a syringe "I" attached to the patient push adapter 15.

**[0059]** The patient push adapter 15 includes a body 301 having respective distal and proximal ends 303, 305. Body 301 of patient push adapter 15 is preferably a one-piece molded plastic part. Distal end 303 of patient push adapter 15 includes a male stem 19 defining a lumen 21, having a seal 23 supported across lumen 21, having guide pins 53, 55 projecting radially outward from on outer surface thereof, and having guide surfaces 57, 59 projecting radially outward from on outer surface thereof. Proximal end 305 of patient push adapter 15 includes a conventional luer connector 307 configured to accept a mating luer connector of a patient I.V. set "IV" (see FIG. 1). Lumen 21 extends through body 301, between seal 23 and luer connector 307, permitting fluid flow between the opening 63 of tip 61 of needle 27 and the luer connector 307, when patient push adapter 15 is properly connected to syringe adapter 11, as described above.



**[0060]** With reference to FIGS. 11-13, it is contemplated that at least one nub 57a, 59a may project from a surface of respective guide surfaces 57, 59 of patient push adapter 15 and which are configured to snap-fit engage respective complementary detents or recesses defined in slots 49, 51 of syringe adapter 11, or more particularly, an appropriately sized annular rib 49a (see FIG. 3) formed in an inner surface of halves 43, 45 of housing 25 of syringe adapter 11. The interaction of nubs 57a, 59a, and complementary detents or recesses defined in slots 49, 51 or annular rib 49a (see FIGS. 3 and 4) of syringe adapter 11 provide a user with audible and/or tactile feedback that patient push adapter 15 and syringe adapter 11 are properly and fully connected to one another.

**[0061]** Guide surfaces 57, 59 of patient push adapter 15 provide a convenient and comfortable surface for a user to grip patient push adapter 15 and to rotate patient push adapter 15 relative to a conventional luer of I.V. set.

**[0062]** Turning now to FIGS. 1 and 15-16, I.V. bag adapter 17 of the closed fluid transfer system 100 of the present disclosure, will be discussed in greater detail. In general, the I.V. bag adapter 17 enables liquid to be delivered to, or extracted from, a conventional I.V. bag "B" (see FIG. 1). The I.V. bag adapter 17 could also be used as a source of ventilation, permitting air to be delivered from a syringe "I" or other source into the I.V. bag to more rapidly drain the I.V. bag "B" of its liquid contents.

**[0063]** The I.V. bag adapter 17 includes a body 401 having respective distal and proximal ends 403, 405, and a spike 407 extending from body 401. Distal end 403 of I.V. bag adapter 17 includes a male stem 19 defining a lumen 21, having a seal 23 supported across lumen 21, having guide pins 51, 53 projecting radially outward from on outer surface thereof, and having guide surfaces 57, 59 projecting radially outward from on outer surface thereof. Body 401 of I.V. bag adapter 17 is preferably a one-piece molded plastic part. Proximal end 405 of body I.V. bag adapter 17 includes a conventional port 409 which receives a conventional tapered male connector (not shown) of a conventional infusion chamber (not shown) into which liquid drips from the I.V. bag "B". Spike 407 is tapered between distal and proximal ends 403, 405 for insertion into a conventional port (not shown) of I.V. bag "B".

**[0064]** Body 401 of I.V. bag adapter 17 includes two ducts 411, 413. First duct 411 is essentially an extension of lumen 21 through spike 407 extending to an opening 415 in spike 407 which would be within I.V. bag "B" when I.V. bag adapter 17 is attached to the I.V. bag "B". Second duct 413 extends between a second opening 417 in spike 407 and a port 409 for attachment to the infusion chamber (not shown). As described above, opening 63 of tip 61 of needle 27 extends into lumen 21 of male stem 19, when I.V. bag adapter 17 is properly connected to syringe adapter 11, to extract or deliver liquid (or gas) through duct 411 while syringe adapter 11 is in the open state.

**[0065]** In accordance with the present disclosure, a

component other than a syringe adapter 11 could be connected to male stem 19 of I.V. bag adapter 17 to deliver gas to I.V. bag "B". Liquid medication delivered through duct 411 may be mixed with the contents of the I.V. bag "B". The liquid in the I.V. bag "B" may then exit the I.V. bag "B" through port 409 and into the infusion chamber for delivery to the patient.

**[0066]** With reference to FIGS. 15 and 16, it is contemplated that at least one nub 57a, 59a may project from a surface of respective guide surfaces 57, 59 of IV. bag adapter 17 and which are configured to snap-fit engage respective complementary detents or recesses defined in slots 49, 51 of syringe adapter 11, or more particularly, an appropriately sized annular channel 49a (see FIG. 3) formed in an inner surface of halves 43, 45 of housing 25 of syringe adapter 11. The interaction of nubs 57a, 59a and complementary detents or recesses defined in slots 49, 51 or annular rib 49a (see FIGS. 3 and 4) of syringe adapter 11 provide a user with audible and/or tactile feedback that I.V. bag adapter 17 and syringe adapter 11 are properly and fully connected to one another.

**[0067]** Turning now to FIGS. 17-24, a syringe adapter, according to another embodiment of the present disclosure, is generally designated as 611. Syringe adapter 611 is substantially similar to syringe adapter 11 and thus will only be discussed in detail hereinbelow to the extent necessary to describe differences in construction and operation therebetween.

**[0068]** As seen in FIGS. 17-19, a respective distal or leading edge 631a, 683a of collar 631 and barrel 683 is chambered to thereby improve the mating of syringe adapter 611 with vial adapter 13, patient push adapter 15, and I.V. bag adapter 17. Additionally, a lead in for each through portion 709, defined in an outer surface of collar 631, has been chamfered so as to better guide the guide pins 53, 55 of any male stem 19 into through portions 709.

**[0069]** As seen in FIG. 18, upper stop wall 703 of each track 699 of collar 631 is oriented at an angle relative to a longitudinal axis of track 699. In particular, upper stop wall 703 is oriented at an angle  $\theta$  of approximately  $85^\circ$  relative to the longitudinal axis of track 699. It is also contemplated that a distal-most surface 713a of ribs 713 is also oriented at an angle that substantially complements the angle of upper stop wall 703. Such an angle of incline for upper stop wall 703 of each track 699 of collar 631 and of distal-most surface 713a of each rib 713, facilitates the ability of collar 631 to rotate relative to housing 25 of syringe adapter 611.

**[0070]** As illustrated in FIG. 19, collar 631 includes helical tracks 715, 717 formed in an outer surface thereof. Each track 715, 717 defines a pitch or angle relative to a longitudinal axis of collar 631 equal to approximately  $50^\circ$ . In this manner, the angle or pitch of helical tracks 715, 717 of collar 631 is greater than the angle or pitch of helical tracks 115, 117 of collar 31.

**[0071]** Referring now to FIGS. 21-24, syringe adapter

611 includes a lock-out feature that prevents an inadvertent rotation of collar 631, relative to housing 25, prior to engagement of seal 73 by the seal 23 of any of the male stems 19. The lock-out feature includes a shuttle 629 having a relatively larger diameter proximal portion 683a of barrel 683 transitioning to a relatively smaller diameter distal portion 683b of barrel 683. The lock-out feature includes a pair of diametrically opposed resilient lock arms 684, 685 formed in collar 631. Each lock arm 684, 685 extends in a radial direction about collar 631 and includes a first end 684a, 685a integrally formed or extending from collar 631, and a free second end 684b, 685b. The free second end 684b, 685b of each lock arm defines a tooth for engaging a respective rib 713.

**[0072]** In use, when shuttle 629 is in a non-depressed condition, as seen in FIGS. 21 and 22, proximal portion 683a of barrel 683 of shuttle 629 is dimensioned so as to press against resilient lock arms 684, 685 formed in collar 631 or act as a barrier or wall against resilient lock arms 684, 685 formed in collar 631, so as to prevent resilient lock arms 684, 685 from deflecting radially inward and disengaging respective ribs 713. Since the tooth of lock arms 684, 685 is in engagement with respective ribs 713 of housing 25, collar 631 is prevented from rotating relative to housing 25 and thus prematurely enabling collar 631 from being depressed (after rotation) relative to housing 25.

**[0073]** As illustrated in FIGS. 23-24, in use, as shuttle 629 is pressed into collar 631, upon a coupling with any of the male stems 19, as described above, distal portion 683b of barrel 683 of shuttle 629 aligns with or comes into registration with lock arms 684, 685 of collar 631. With the resilient lock arms 684, 685 overlying distal portion 683b of barrel 683 of shuttle 629, distal portion 683b of barrel 683 of shuttle 629 is spaced a distance radially inward of lock arms 684, 685 by an amount sufficient to allow lock arms 684, 685 to deflect radially inward and snap over respective ribs 713 as collar 631 is rotated relative to housing 25.

**[0074]** As seen in FIGS. 22 and 24, lock arms 684, 685 are mirrored about a plane extending parallel to a longitudinal axis of collar 631 and extending substantially equally between lock arms 684, 685.

**[0075]** Referring now to FIGS. 25-31, closed fluid transfer system 100, of the present disclosure, may include a universal vial adapter 813. Generally, universal vial adapter 813 connects to various sized caps or necks of vials holding a liquid to be extracted or into which liquid is to be delivered. For example, universal vial adapter 813 may be configured to connect to vials having either a 20mm vial cap or a 28mm vial cap. While 20mm and 28mm vial caps are identified, it is contemplated that universal vial adapter 813 may be configured and dimensioned to accommodate and/or connect to any size cap of any vial or the like.

**[0076]** Universal vial adapter 813 includes three, equally radially spaced apart first claws 815a, 815b, 815c supported on a hub 814 and which are configured to en-

gage an outer rim of a relatively smaller diametered cap (e.g., a 20mm vial cap as seen in FIG. 25). Universal vial adapter 813 also includes three, equally radially spaced apart second claws 816a, 816b, 816c supported on a hub 814 and which are configured to engage an outer rim of a relatively larger diametered cap (e.g., a 28mm vial cap as seen in FIGS. 28). Each second claw 816a, 816b, 816c is interposed between adjacent first claws 815a, 815b, 815c.

**[0077]** It is contemplated that each claw 815a, 815b, 815c and each claw 816a, 816b, 816c is biased to a closed condition.

**[0078]** It is further contemplated that hub 814 is slidably disposed within base 201 of universal vial adapter 813. Universal vial adapter 813 includes a locking system including at least one first latch arm 817 having a shoulder 817a which engages a first shoulder 201a of base 201 when hub 814 is in a fully pressed-in condition. The locking system of universal vial adapter 813 includes at least one second latch arm 818 having a shoulder 818a which engages a second shoulder 201b of base 201 when hub 814 is in a fully non-pressed-in condition.

**[0079]** In use, the at least one second latch arm 818 of the locking system maintains hub 814 in the fully non-pressed-in condition until a relatively smaller cap is fully engaged by first claws 815a, 815b, 815c or until relatively larger cap is fully engaged by second claws 816a, 816b, 816c. Once the cap is fully engaged by first claws 815a, 815b, 815c or second claws 816a, 816b, 816c, the at least one second latch arm 818 of the locking system disengages from second shoulder 201b of base 201, allowing hub 814 to be moved to the pressed-in condition. When hub 814 is moved to the pressed-in condition, the shoulder 817a of the at least one first latch arm 817 engages the first shoulder 201a of base 201 to maintain hub 814 in the pressed-in condition.

**[0080]** An important aspect of the present disclosure is the alignment and contact of seal 73 of syringe adapters 11 or 611 with seal 23 of male stems 19 of patient push adapter 13, vial adapters 15 and 815, and I.V. bag adapter 17. Ensuring that seals 73 and 23 are in proper alignment with one another is important to ensure that needle 27 penetrates through both seals 73 and 23 upon complete coupling/connecting of syringe adapters 11, 611 with patient push adapter 13, vial adapters 15 and 815, and I.V. bag adapter 17.

**[0081]** Another important aspect of the present disclosure is the ability of the user to swab, wipe, clean and/or disinfect seals 73 and 23 prior to or following their use.

**[0082]** Also in accordance with the present disclosure, each seal 23 and 73 is provided with a constant pressure radially inward along an entire length of seal 23, 73 such that the distal and proximal surfaces of seals 23, 73 are convex or arc outward. As such, the seal to seal contact between abutting seals 23 and 73 is improved.

**[0083]** While the above disclosure and related figures illustrate syringes, vials, I.V. sets, and I.V. bags as exemplary embodiments, it is envisioned and within the scope

of the present disclosure that any of the adapters described herein may be used in cooperation with any fluid container, such as, for example, bottles, test tubes, trays, tubs, vats, jars, bathes, pools, pressure vessels, balloons, ampoules, etc.

**[0084]** It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope of the claims appended thereto.

**Claims**

1. A vial adapter (13) for a closed fluid transfer system, the vial adapter including a base (201) defining an opening (217) having a plurality of retainers (219) extending around the opening (217) of the base (201) and being configured to snap-fit connect to a neck ("N") of a vial ("V"), **characterized in that** the base (201) defines a lower inner annular rim and an outer annular rim and a cavity therebetween, the vial adapter (13) further including:

a cover (215) supported on the outer rim of the base (201), wherein an expansion chamber (207) is defined within the cover (215) and the base (201);

an adapter support (203) situated within the cavity of the base (201), the adapter support (203) including:

an annular flange for seating on the lower inner annular rim of the base (201) and forming a fluid tight seal therebetween;

an annular wall extending from the annular flange and defining an upper inner annular rim, wherein the cover is also supported on the upper inner annular rim;

a male stem (19) extending in a first direction from the annular flange, the male stem (19) for selective connection to and insertion into an open distal end (33) of a syringe adapter (11), the male stem (19) defining a lumen (21) extending therethrough;

a pair of opposed guide pins (53, 55) extending radially outward from the male stem (19);

a pair of opposed guide surfaces (57, 59) extending radially outward from the male (19) stem at a location proximal of the guide pins (53, 55) and being in registration with the guide pins (53, 55); and

a seal (23) extending across the lumen (21) of the male stem (19); and

a spike (205) extending in a second direction from the annular flange, wherein the spike (205) extends into the opening (217) of the base (201), wherein the spike (205) includes a first lumen (223) being in fluid communication with the lumen (21) of the male stem (19), and wherein the spike (205) includes a second lumen (225) being in fluid communication with the expansion chamber (207); and

a bladder (227) extending between the inner upper annular rim and the outer annular rim of the base (201).

2. The vial adapter (13) according to claim 1 and a syringe adapter (11), wherein the vial adapter (13) is configured to move the syringe adapter (11) from a closed state to an open state, the syringe adapter (11) including:

a housing (25) defining an open distal end (33) and an open proximal end (35), the housing (25) defining a pair of opposed longitudinally extending slots (49, 51) opening from the open distal end (33) of the housing (25), the housing (25) including a pair of opposed longitudinally extending ribs (25a) projecting from an inner surface thereof;

a base (47) supported in the open proximal end (33) of the housing (25) and including a syringe adapter luer connector (69);

a collar (31) slidably and rotatably supported in the housing (25), the collar defining a longitudinal opening therethrough, the collar (31) defining a pair of opposed L-shaped tracks (99) formed in an outer surface thereof and configured to receive a respective longitudinally extending rib (25a) therein, the collar (31) defines a pair of opposed helical tracks (115, 117) opening from a distal surface of the collar (31), the opposed helical tracks (115, 117) being aligned with a respective slot of the housing (25) when the collar (31) is in a distal-most position;

a shuttle (29) slidably extending through longitudinal opening of the collar (31), the shuttle (29) defining a shuttle lumen (81) extending longitudinally therethrough;

a barrel (83) supported on and extending over a distal end of the shuttle (29), the barrel (83) defining a central opening aligned with the shuttle lumen (81); and

a biasing member (95) interposed between the collar (31) and the shuttle (29) for urging the collar (31) away from the shuttle (29);

a syringe first adapter seal (73) being interposed between the shuttle (29) and the barrel (83), wherein the syringe first adapter seal (73) extends across the shuttle lumen (81) and the central opening of the barrel (83); and

a needle (27) defining a lumen (67) therethrough, the needle (27) having a proximal end supported in the base (47) such that the lumen (67) of the needle (27) is in fluid communication with the luer connector (69), the needle (27) having a sharpened distal tip (61) disposed within the lumen (81) of the shuttle (29) when the shuttle (29) is in a distal-most position; wherein the vial adapter (13) moves the syringe adapter (11) from the closed state to the open state upon:

inserting the guide pins (53, 55) of the male stem (19) of the vial adapter (13) into the respective slots (49, 51) of the housing (25) of the syringe adapter (11), whereby the seal (23) of the vial adapter (13) abuts the seal (73) of the syringe adapter (11);

advancing the male stem (19) of the vial adapter (13) into the open distal end (33) of the housing (25) such that the guide pins (53, 55) enter into the respective helical track (115, 117) of the collar (31) to (1) rotate the collar (31) relative to the housing (25) of the syringe adapter (11) and (2) align the ribs (25a) of the housing (25) with a through portion (109) of the collar (31); and further advancing the male stem (19) of the vial adapter (13) into the open distal end (33) of the housing (25) causing the collar (31) to move proximally which causes the shuttle (29) to move proximally until the tip (61) of the needle (27) penetrates through the abutting seals (23, 73), whereby the syringe adapter (11) is in the open state and fluidly interconnects a syringe ("I") with the vial adapter (13).

3. The vial adapter (13) according to claim 1, wherein the spike (205) of the vial adapter (13) penetrates a septum ("S") of the vial ("V") upon a connection of the base (201) of the vial adapter (13) to a neck ("N") of the vial ("V").
4. The vial adapter (13) according to claim 2, wherein when a syringe ("I") is connected to the syringe adapter (11), and when the syringe adapter (11) is connected to the vial adapter (13), and when the vial adapter (13) is connected to the vial ("V"), the syringe ("I") is in closed fluid communication with the vial ("V").
5. The vial adapter (13) according to claim 4, wherein when the syringe ("I") is connected to the syringe adapter (11), and when the syringe adapter (11) is connected to the vial adapter (13), the tip (61) of the needle (27) of the syringe adapter (11) penetrates the abutting seals (73, 23) of the syringe adapter (11) and the vial adapter (13) and when the vial adapter (13) is connected to the vial ("V"), the syringe ("I") is in closed fluid communication with the vial ("V").

6. The vial adapter (13) according to claim 4, wherein air from the syringe ("I") is injectable into a cavity of the vial adapter (13) defined between the bladder (227), and the base (201) and the adapter support (203), through a fluid passage defined by the needle (27) of the syringe adapter (13), the lumen (21) of the male stem (19), the first lumen (223) of the spike (205), the vial ("V") and the second lumen (225) of the spike (205).
7. The vial adapter (13) according to claim 1, wherein the seal (23) is made from polyisoprene.
8. The vial adapter (13) and the syringe adaptor (11) according to claim 2, wherein each seal (23, 73) is made from polyisoprene.

### Patentansprüche

1. Phiolenadapter (13) für ein geschlossenes Flüssigkeitstransfersystem, wobei der Phiolenadapter eine Basis (201) umfasst, die eine Öffnung (217) mit einer Vielzahl von Haltern (219) definiert, die sich um die Öffnung (217) der Basis (201) erstreckt und so konfiguriert ist, dass sie durch Einrasten mit einem Hals ("N") einer Phiole ("V") verbunden wird, **dadurch gekennzeichnet, dass** die Basis (201) einen unteren inneren ringförmigen Rand und einen äußeren ringförmigen Rand und einen Hohlraum dazwischen definiert, wobei der Phiolenadapter (13) ferner umfasst:

eine Abdeckung (215), die auf dem äußeren ringförmigen Rand der Basis (201) getragen wird, wobei eine Expressionskammer (207) innerhalb der Abdeckung (215) und der Basis (201) definiert ist;

eine Adapterstütze (203), die sich innerhalb des Hohlraums der Basis (201) befindet, wobei die Adapterstütze (203) Folgendes umfasst:

einen ringförmigen Flansch zum Auflegen auf dem unteren inneren ringförmigen Rand der Basis (201) und zum Bilden einer fluidichten Abdichtung dazwischen;

eine ringförmige Wand, die sich vom ringförmigen Flansch erstreckt und einen oberen inneren ringförmigen Rand definiert, wobei die Abdeckung auch auf dem oberen inneren ringförmigen Rand getragen wird; ein Einsteckrohr (19), das sich in einer ersten Richtung vom ringförmigen Flansch erstreckt, wobei das Einsteckrohr (19) zur selektiven Verbindung mit und Einführung in ein offenes distales Ende (33) eines Spritzenadapters (11) dient, wobei das Einsteckrohr (19) ein Lumen (21) definiert, das sich

dadurch erstreckt;  
 ein Paar gegenüberliegender Führungsstifte (53, 55), die sich radial nach außen vom Einsteckrohr (19) erstrecken;  
 ein Paar gegenüberliegender Führungsflächen (57, 59), die sich radial nach außen vom Einsteckrohr (19) an einer Stelle proximal von den Führungsstiften (53, 55) erstrecken und mit den Führungsstiften (53, 55) ausgerichtet sind; und  
 eine Dichtung (23), die sich über das Lumen (21) des Einsteckrohrs (19) erstreckt; und

einen Dorn (205), der sich in einer zweiten Richtung vom ringförmigen Flansch erstreckt, wobei sich der Dorn (205) in die Öffnung (217) der Basis (201) erstreckt, wobei der Dorn (205) ein erstes Lumen (223) umfasst, das in Fluidkommunikation mit dem Lumen (21) des Einsteckrohrs (19) ist, und wobei der Dorn (205) ein zweites Lumen (225) umfasst, das in Fluidkommunikation mit der Expansionskammer (207) ist; und  
 eine Blase (227), die sich zwischen dem inneren oberen ringförmigen Rand und dem äußeren ringförmigen Rand der Basis (201) erstreckt.

2. Phiolenadapter (13) nach Anspruch 1 und Spritzenadapter (11), wobei der Phiolenadapter (13) so konfiguriert ist, dass er den Spritzenadapter (11) von einem geschlossenen Zustand in einen offenen Zustand bewegen kann, wobei der Spritzenadapter (11) Folgendes umfasst:

ein Gehäuse (25), das ein offenes distales Ende (33) und ein offenes proximales Ende (35) definiert, wobei das Gehäuse (25) ein Paar gegenüberliegender in Längsrichtung erstreckender Schlitze (49, 51) definiert, die sich vom offenen distalen Ende (33) des Gehäuses (25) öffnen, wobei das Gehäuse (25) ein Paar gegenüberliegender in Längsrichtung erstreckender Rippen (25a) umfasst, die aus einer inneren Fläche davon vorstehen;  
 eine Basis (47), die im offenen proximalen Ende (33) des Gehäuses (25) getragen wird und einen Spritzenadapter-Luer-Verbinder (69) umfasst;  
 einen Kragen (31), der gleitend und drehbar im Gehäuse (25) getragen wird, wobei der Kragen eine Längsöffnung durch diesen definiert, wobei der Kragen (31) ein Paar gegenüberliegender L-förmiger Schienen (99) definiert, die in einer äußeren Fläche von diesen gebildet werden und so konfiguriert sind, dass sie eine entsprechende in Längsrichtung erstreckende Rippe (25a) in diesen empfängt, wobei der Kragen (31) ein Paar gegenüberliegender schraubenförmiger Schienen (115, 117) umfasst, die sich von einer distalen Fläche des Kragens (31) öffnen, wobei

die gegenüberliegenden schraubenförmigen Schienen (115, 117) in Flucht mit einem entsprechenden Schlitz des Gehäuses (25) sind, wenn sich der Kragen (31) an einer am weitesten distal gelegenen Position befindet;  
 einen Schlitten (29), der sich gleitend durch die Längsöffnung des Kragens (31) erstreckt, wobei der Schlitten (29) ein Schlittenlumen (81) definiert, das sich in Längsrichtung durch diesen erstreckt;  
 einen Zylinder (83), der auf einem distalen Ende der Schiene (29) getragen wird und sich über das distale Ende der Schiene (29) erstreckt, wobei der Zylinder (83) eine zentrale Öffnung definiert, die in Flucht mit dem Schlittenlumen (81) ist; und  
 ein Vorspannelement (95), das zwischen dem Kragen (31) und der Schiene (29) angeordnet ist, um den Kragen (31) vom Schlitten (29) wegzuzwingen;

eine erste Spritzenadapterdichtung (73), die zwischen dem Schlitten (29) und dem Zylinder (83) angeordnet ist, wobei sich die erste Spritzenadapterdichtung (73) über das Schlittenlumen (81) und die zentrale Öffnung des Zylinders (83) erstreckt; und  
 eine Nadel (27), die ein Lumen (67) durch diese definiert; wobei die Nadel (27) über ein proximales Ende verfügt, das in der Basis (47) getragen wird, sodass das Lumen (67) der Nadel (27) in Fluidkommunikation mit dem Luer-Verbinder (69) ist, wobei die Nadel (27) über eine geschärfte distale Spitze (61) verfügt, die sich innerhalb des Lumens (81) des Schlittens (29) befindet, wenn sich der Schlitten (29) in einer am weitesten distal gelegenen Position befindet;  
 wobei der Phiolenadapter (13) den Spritzenadapter (11) vom geschlossenen Zustand in den offenen Zustand bewegt durch:

Einfügen der Führungsstifte (53, 55) des Einsteckrohrs (19) des Phiolenadapters (13) in die entsprechenden Schlitze (49, 51) des Gehäuses (25) des Spritzenadapters (11), wobei die Dichtung (23) des Phiolenadapters (13) an die Dichtung (73) des Spritzenadapters (11) angrenzt;  
 Vorschieben des Einsteckrohrs (19) des Phiolenadapters (13) in das offene distale Ende (33) des Gehäuses (25), sodass die Führungsstifte (53, 55) in die entsprechende schraubenförmige Schiene (115, 117) des Kragens (31) eintreten, um (1) den Kragen (31) relativ zu dem Gehäuse (25) des Spritzenadapters (11) zu rotieren und (2) die Rippen (25a) des Gehäuses (25) mit einem Durchgangsabschnitt (109) des Kragens (31) zu fluchten; und  
 ferner Vorschieben des Einsteckrohrs (19) des

- Phiolenadapters (13) in das offene distale Ende (33) des Gehäuses (25), wodurch der Kragen (31) proximal verschoben wird, was dazu führt, dass der Schlitten (29) proximal verschoben wird, bis die Spitze (61) der Nadel (27) durch die aneinandergrenzenden Dichtungen (23, 73) dringt, wobei sich der Spritzenadapter (11) im offenen Zustand befindet und eine Spritze ("I") mit dem Phiolenadapter (13) fluidisch verbindet.
3. Phiolenadapter (13) nach Anspruch 1, wobei der Dorn (205) des Phiolenadapters (13) durch ein Septum ("S") der Phiole ("V") bei einer Verbindung der Basis (201) des Phiolenadapters (13) zu einem Hals ("N") der Phiole ("V") dringt.
  4. Phiolenadapter (13) nach Anspruch 2, wobei dann, wenn eine Spritze ("I") mit dem Spritzenadapter (11) verbunden ist und wenn der Spritzenadapter (11) mit dem Phiolenadapter (13) verbunden ist und wenn der Phiolenadapter (13) mit der Phiole ("V") verbunden ist, die Spritze ("I") in geschlossener Fluidkommunikation mit der Phiole ("V") ist.
  5. Phiolenadapter (13) nach Anspruch 4, wobei dann, wenn die Spritze ("I") mit dem Spritzenadapter (11) verbunden ist und wenn der Spritzenadapter (11) mit dem Phiolenadapter (13) verbunden ist, die Spitze (61) der Nadel (27) des Spritzenadapters (11) durch die aneinandergrenzenden Dichtungen (73, 23) des Spritzenadapters (11) und den Phiolenadapter (13) dringt, und wenn der Phiolenadapter (13) mit der Phiole ("V") verbunden ist, die Spritze ("I") in geschlossener Fluidverbindung mit der Phiole ("V") ist.
  6. Phiolenadapter (13) nach Anspruch 4, wobei Luft von der Spritze ("I") in einen Hohlraum des Phiolenadapters (13), der zwischen der Blase (227) und der Basis (201) und der Adapterstütze (203) definiert ist, durch einen Fluiddurchlass injizierbar ist, der definiert wird durch die Nadel (27) des Spritzenadapters (13), das Lumen (21) des Einsteckrohrs (19), das erste Lumen (223) des Dorns (205), die Phiole ("V") und das zweite Lumen (225) des Dorns (205).
  7. Phiolenadapter (13) nach Anspruch 1, wobei die Dichtung (23) aus Polyisopren besteht.
  8. Phiolenadapter (13) und Spritzenadapter (11) nach Anspruch 2, wobei jede Dichtung (23, 73) aus Polyisopren besteht.
- Revendications**
1. Adaptateur pour flacon (13) pour un système de transfert de fluide fermé, l'adaptateur pour flacon comprenant une base (201) définissant une ouverture (217) ayant une pluralité d'éléments de retenue (219) s'étendant autour de l'ouverture (217) de la base (201) et configurés pour se raccorder par enclenchement à un col (« N ») d'un flacon (« V »), **caractérisé en ce que** la base (201) définit un rebord annulaire intérieur inférieur et un rebord annulaire extérieur et une cavité entre ceux-ci, l'adaptateur pour flacon (13) comprenant en outre :
    - un recouvrement (215) supporté sur le rebord extérieur de la base (201), dans lequel une chambre d'expansion (207) est définie à l'intérieur du recouvrement (215) et de la base (201) ;
    - un support d'adaptateur (203) situé à l'intérieur de la cavité de la base (201), le support d'adaptateur (203) comprenant .
      - une bride annulaire pour se mettre en appui sur le rebord annulaire intérieur inférieur de la base (201) et former un joint étanche au fluide entre ceux-ci ;
      - une paroi annulaire s'étendant de la bride annulaire et définissant un rebord annulaire intérieur supérieur, dans lequel le recouvrement est également supporté sur le rebord annulaire intérieur supérieur ;
      - une tige mâle (19) s'étendant dans une première direction depuis la bride annulaire, la tige mâle (19) pour le raccordement sélectif à et l'insertion dans une extrémité distale ouverte (33) d'un adaptateur pour seringue (11), la tige mâle (19) définissant un lumen (21) s'étendant à travers celle-ci ;
      - une paire de broches de guidage opposées (53, 55) s'étendant radialement vers l'extérieur de la tige mâle (19) ;
      - une paire de surfaces de guidage opposées (57, 59) s'étendant radialement vers l'extérieur de la tige mâle (19) à un emplacement proximal des broches de guidage (53, 55) et étant en enregistrement avec les broches de guidage (53, 55) ; et
      - un joint (23) s'étendant à travers le lumen (21) de la tige mâle (19) ; et
    - une pointe (205) s'étendant dans une deuxième direction depuis la bride annulaire, dans lequel la pointe (205) s'étend dans l'ouverture (217) de la base (201), dans lequel la pointe (205) comprend un premier lumen (223) en communication fluide avec le lumen (21) de la tige mâle (19), et dans lequel la pointe (205) comprend un deuxième lumen (225) en communication fluide avec la chambre d'expansion (207) ; et
    - une vessie (227) s'étendant entre le rebord annulaire supérieur intérieur et le rebord annulaire extérieur de la base (201).
  2. Adaptateur pour flacon (13) selon la revendication 1

et un adaptateur pour seringue (11), dans lequel l'adaptateur pour flacon (13) est configuré pour déplacer l'adaptateur pour seringue (11) d'un état fermé à un état ouvert, l'adaptateur pour seringue (11) comprenant :

un boîtier (25) définissant une extrémité distale ouverte (33) et une extrémité proximale ouverte (35), le boîtier (25) définissant une paire de fentes opposées s'étendant longitudinalement (49, 51) s'ouvrant depuis l'extrémité distale ouverte (33) du boîtier (25), le boîtier (25) comprenant une paire de nervures opposées s'étendant longitudinalement (25a) faisant saillie d'une surface intérieure de celui-ci ;

une base (47) supportée dans l'extrémité proximale ouverte (33) du boîtier (25) et comprenant un connecteur Luer d'adaptateur pour seringue (69) ;

un collier (31) supporté de manière coulissante et en rotation dans le boîtier (25), le collier définissant une ouverture longitudinale à travers celui-ci, le collier (31) définissant une paire de pistes opposées en forme de L (99) formées dans une surface extérieure de celui-ci et configurées pour recevoir une nervure respective s'étendant longitudinalement (25a) à l'intérieur de celui-ci, le collier (31) définit une paire de pistes hélicoïdales opposées (115, 117) s'ouvrant depuis une surface distale du collier (31), les pistes hélicoïdales opposées (115, 117) étant alignées avec une fente respective du boîtier (25) lorsque le collier (31) est dans une position la plus distale ; une navette (29) s'étendant de manière coulissante à travers une ouverture longitudinale du collier (31), la navette (29) définissant un lumen de navette (81) s'étendant longitudinalement à travers celle-ci ;

un canon (83) supporté sur et s'étendant sur une extrémité distale de la navette (29), le canon (83) définissant une ouverture centrale alignée avec le lumen de navette (81) ; et

un élément de sollicitation (95) intercalé entre le collier (31) et la navette (29) pour pousser le collier (31) à s'éloigner de la navette (29) ;

un premier joint d'adaptateur pour seringue (73) intercalé entre la navette (29) et le canon (83), dans lequel le premier joint d'adaptateur pour seringue (73) s'étend à travers le lumen de navette (81) et l'ouverture centrale du canon (83) ; et

une aiguille (27) définissant un lumen (67) à travers celle-ci, l'aiguille (27) ayant une extrémité proximale supportée dans la base (47) de sorte que le lumen (67) de l'aiguille (27) est en communication fluïdique avec le connecteur Luer (69), l'aiguille (27) ayant une pointe distale aiguillée (61) disposée à l'intérieur du lumen (81) de

la navette (29) lorsque la navette (29) est dans une position la plus distale ;

dans lequel l'adaptateur pour flacon (13) déplace l'adaptateur pour seringue (11) de l'état fermé à l'état ouvert lors de :

l'insertion des broches de guidage (53, 55) de la tige mâle (19) de l'adaptateur pour flacon (13) dans les fentes respectives (49, 51) du boîtier (25) de l'adaptateur pour seringue (11), moyennant quoi le joint (23) de l'adaptateur pour flacon (13) vient en butée contre le joint (73) de l'adaptateur pour seringue (11) ;

l'avance de la tige mâle (19) de l'adaptateur pour flacon (13) dans l'extrémité distale ouverte (33) du boîtier (25) de sorte que les broches de guidage (53, 55) entrent dans la piste hélicoïdale respective (115, 117) du collier (31) pour (1) tourner le collier (31) par rapport au boîtier (25) de l'adaptateur pour seringue (11) et (2) aligner les nervures (25a) du boîtier (25) avec une portion traversante (109) du collier (31) ; et l'avance supplémentaire de la tige mâle (19) de l'adaptateur pour flacon (13) dans l'extrémité distale ouverte (33) du boîtier (25) amenant le collier (31) à se déplacer de manière proximale ce qui amène la navette (29) à se déplacer de manière proximale jusqu'à ce que la pointe (61) de l'aiguille (27) pénètre à travers les joints en butée (23, 73), moyennant quoi l'adaptateur de seringue (11) est dans l'état ouvert et raccorde fluidiquement une seringue (« I ») avec l'adaptateur pour flacon (13).

3. Adaptateur pour flacon (13) selon la revendication 1, dans lequel la pointe (205) de l'adaptateur pour flacon (13) pénètre dans un septum (« S ») du flacon (« V ») lors d'un raccordement de la base (201) de l'adaptateur pour flacon (13) à un col (« N ») du flacon (« V »).

4. Adaptateur pour flacon (13) selon la revendication 2, dans lequel lorsqu'une seringue (« I ») est raccordée à l'adaptateur pour seringue (11), et lorsque l'adaptateur pour seringue (11) est raccordé à l'adaptateur pour flacon (13), et lorsque l'adaptateur pour flacon (13) est raccordé au flacon (« V »), la seringue (« I ») est en communication fluïdique fermée avec le flacon (« V »).

5. Adaptateur pour flacon (13) selon la revendication 4, dans lequel lorsque la seringue (« I ») est raccordée à l'adaptateur pour seringue (11), et lorsque l'adaptateur pour seringue (11) est raccordé à l'adaptateur pour flacon (13), la pointe (61) de l'aiguille (27) de l'adaptateur pour seringue (11) pénètre dans les joints en butée (73, 23) de l'adaptateur

de seringue (11) et l'adaptateur pour flacon (13) et lorsque l'adaptateur pour flacon (13) est raccordé au flacon (« V »), la seringue (« I ») est en communication fluide fermée avec le flacon (« V »).

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6. Adaptateur pour flacon (13) selon la revendication 4, dans lequel de l'air de la seringue (« I ») est injectable dans une cavité de l'adaptateur pour flacon (13) définie entre la vessie (227), et la base (201) et le support d'adaptateur (203), à travers un passage de fluide défini par l'aiguille (27) de l'adaptateur pour seringue (13), le lumen (21) de la tige mâle (19), le premier lumen (223) de la pointe (205), le flacon (« V ») et le deuxième lumen (225) de la pointe (205).

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7. Adaptateur pour flacon (13) selon la revendication 1, dans lequel le joint (23) est réalisé en polyisoprène.

8. Adaptateur pour flacon (13) et adaptateur pour seringue (11) selon la revendication 2, dans lequel chaque joint (23, 73) est réalisé en polyisoprène.

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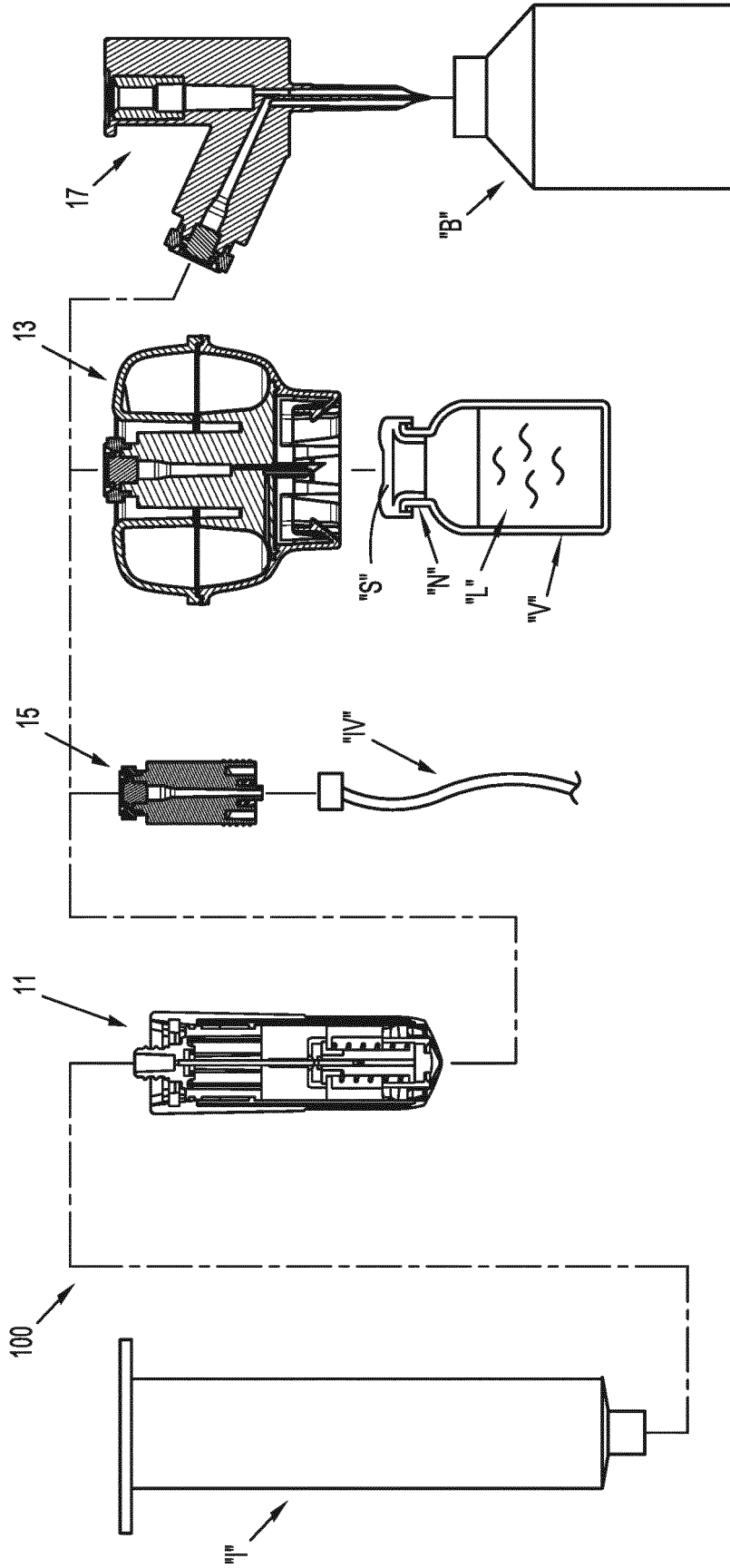
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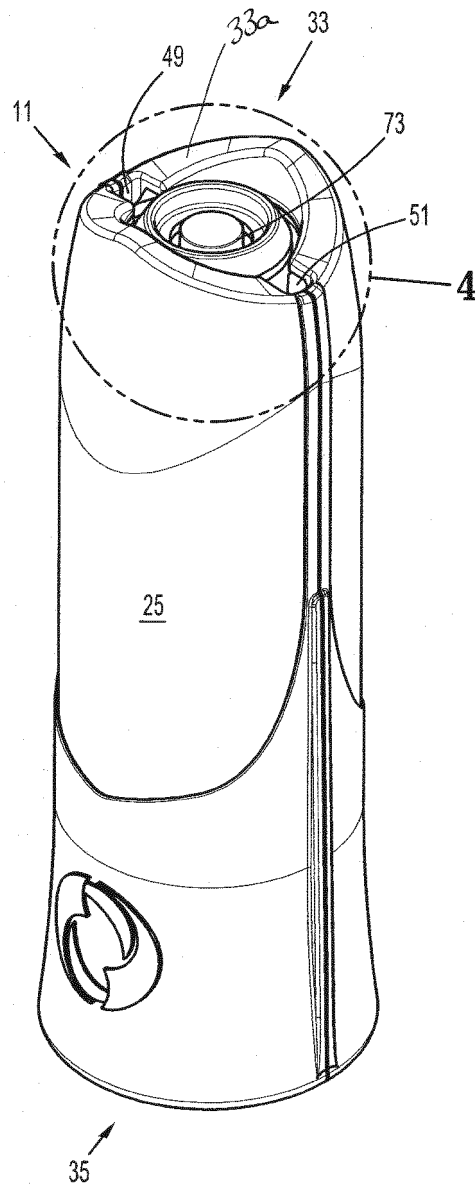
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**FIG. 1**



**FIG. 2**

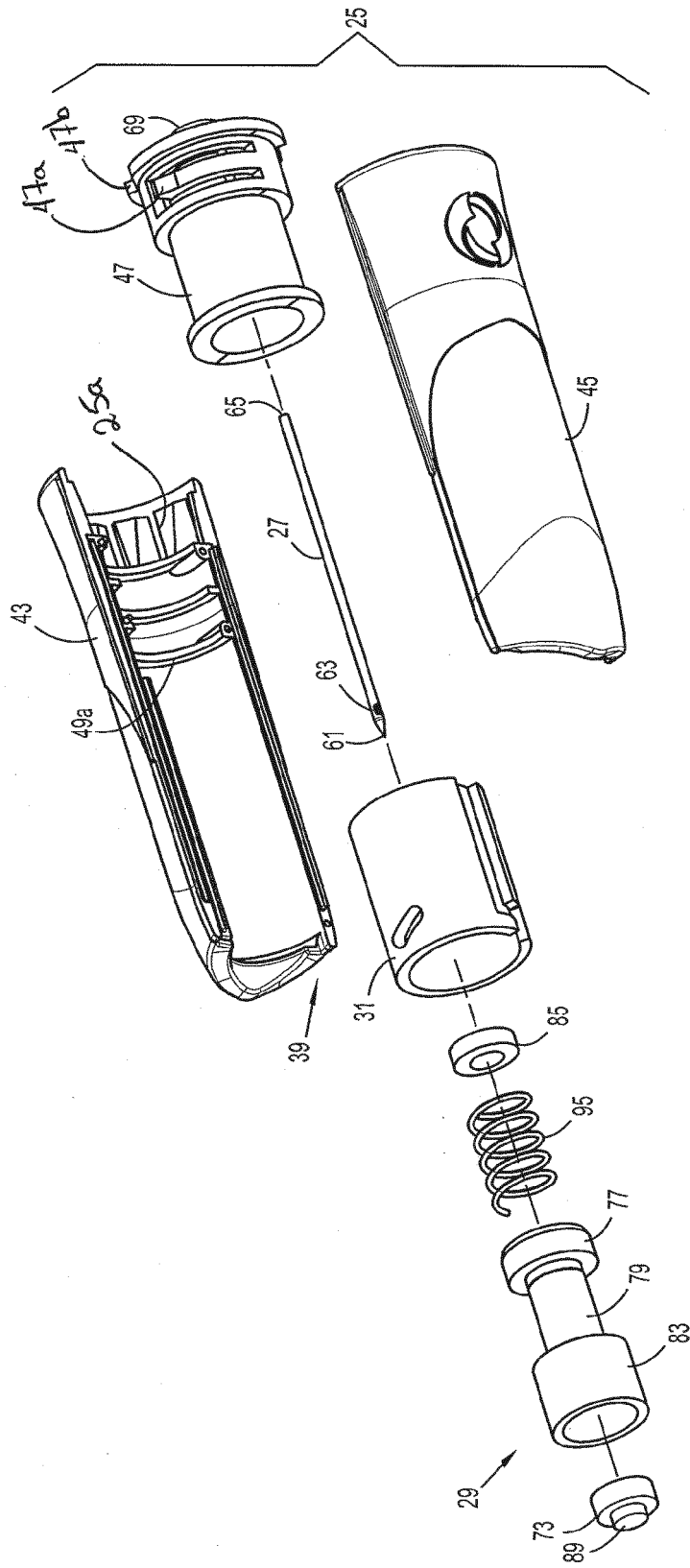
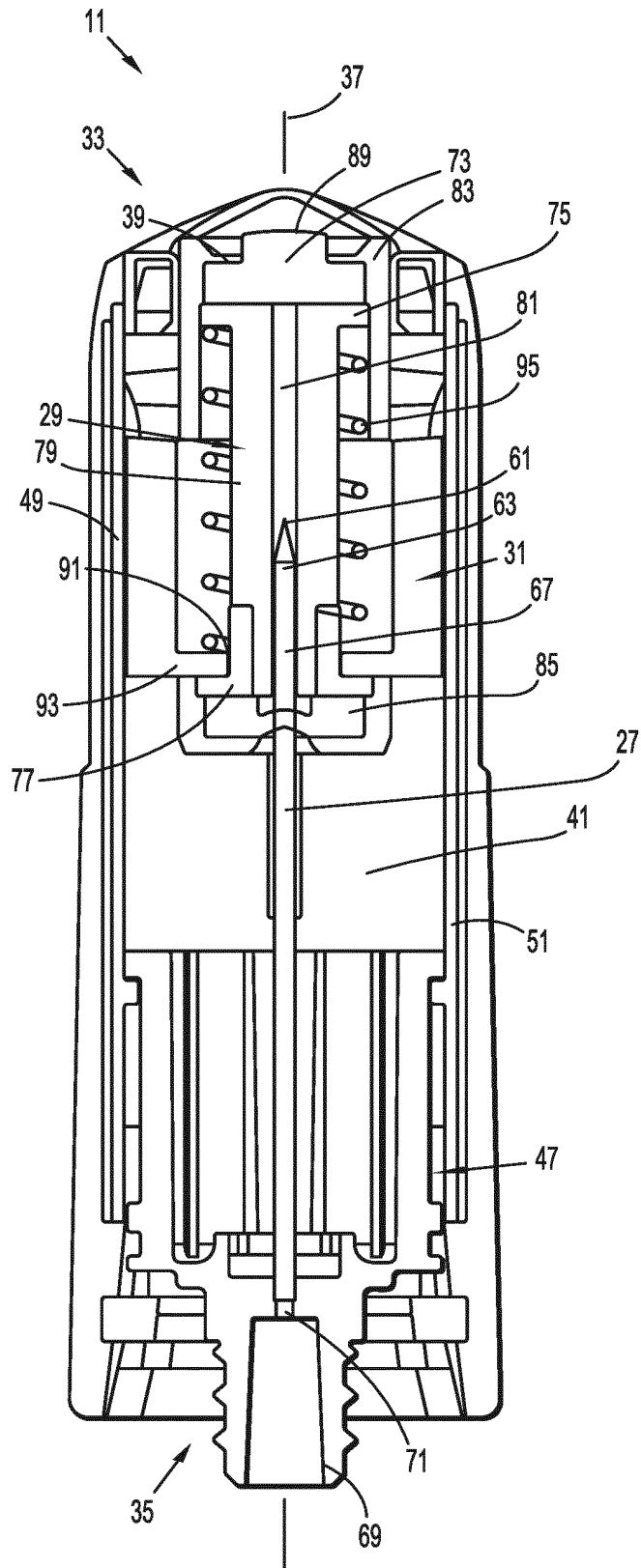
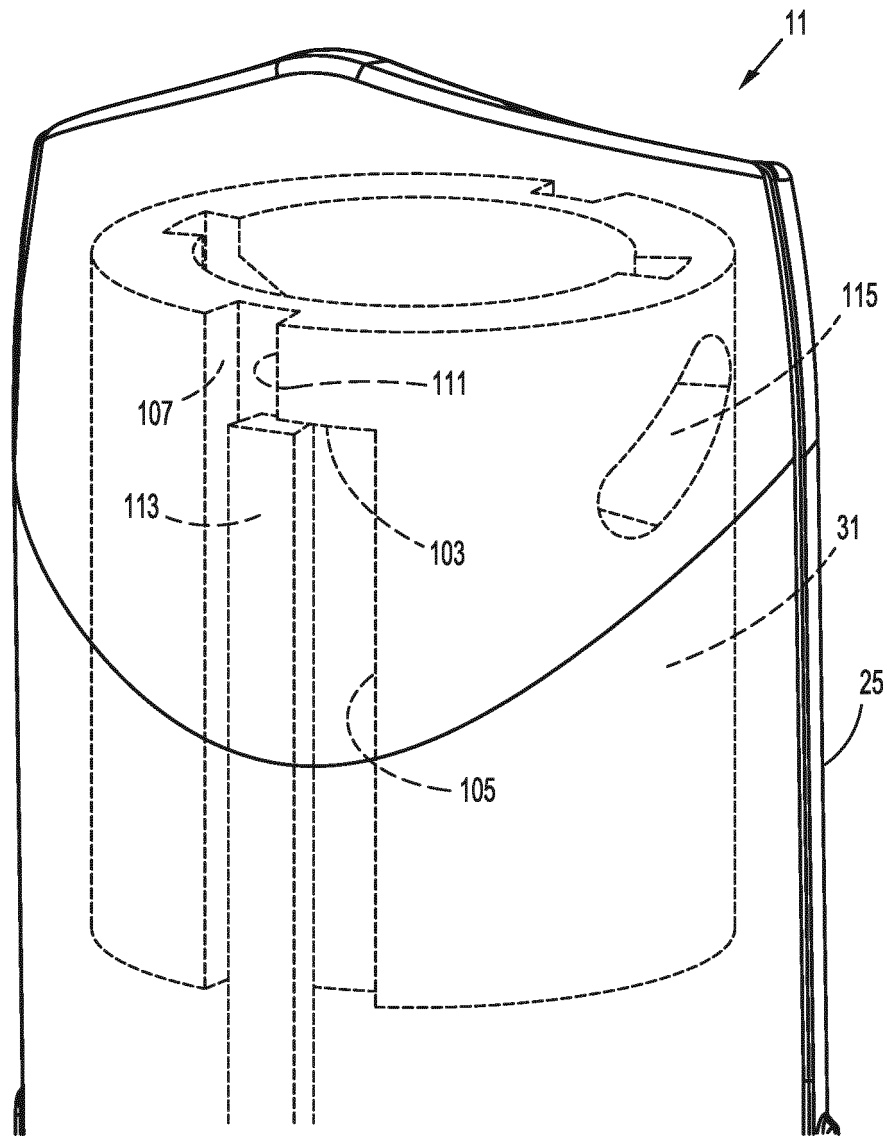


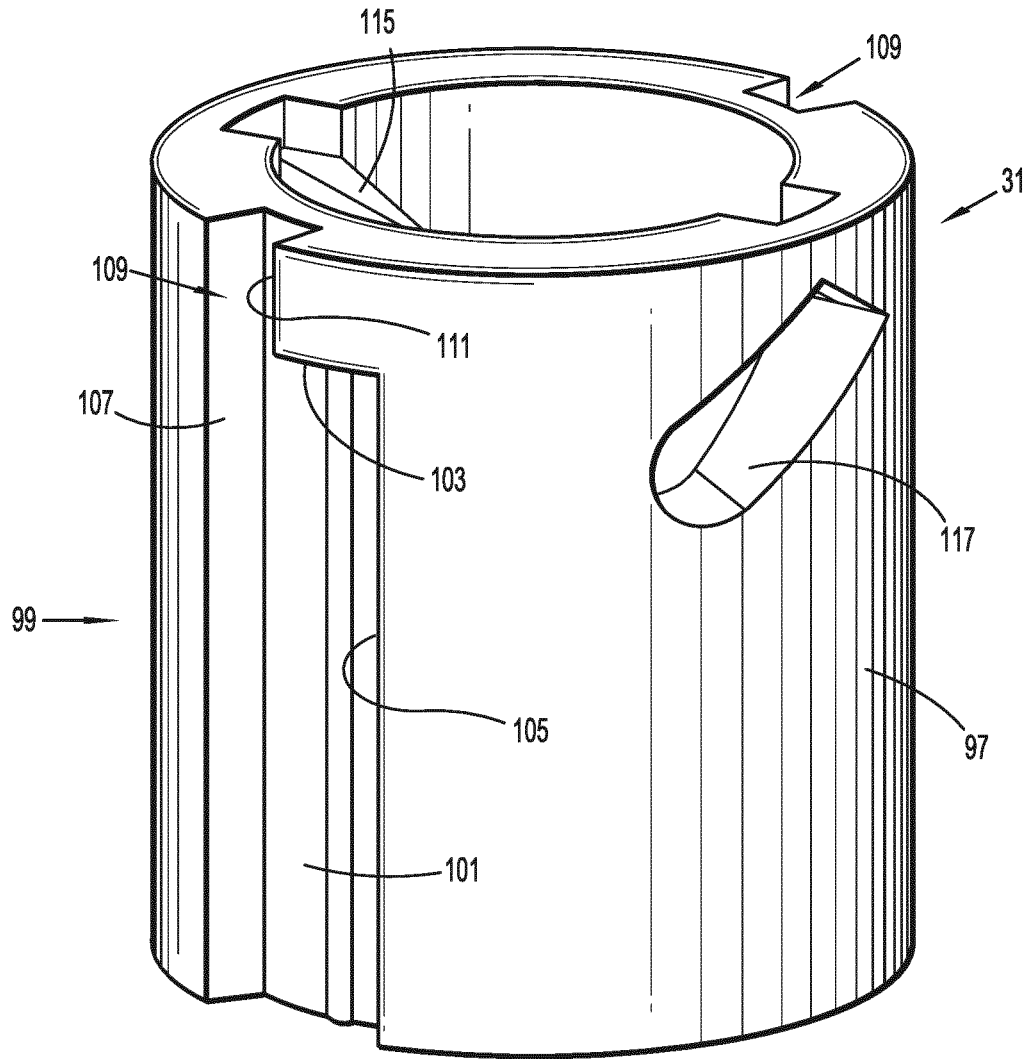
FIG. 3



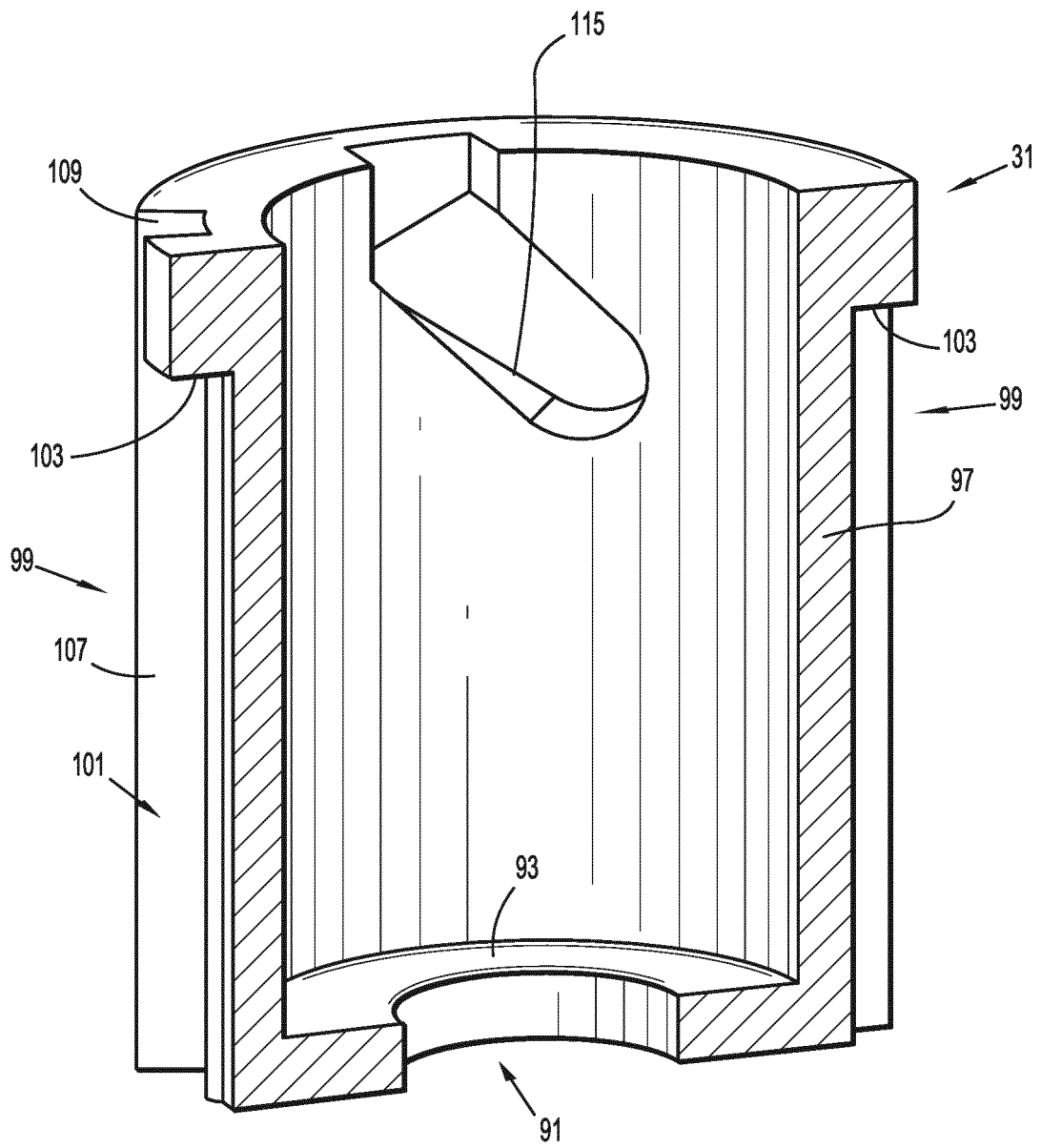
**FIG. 4**



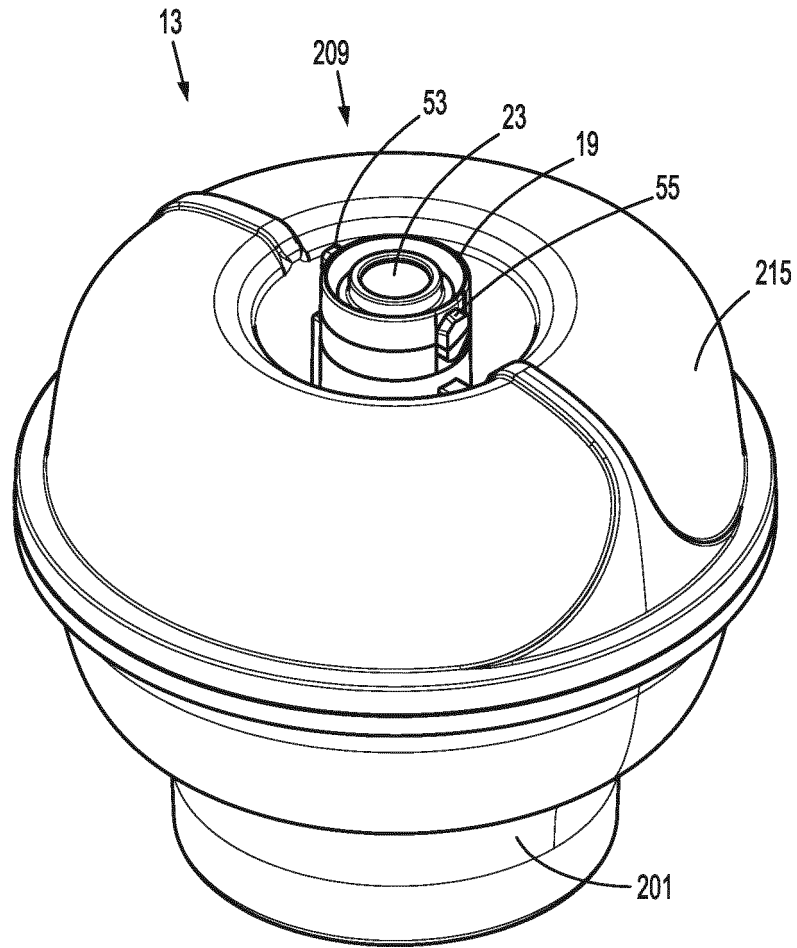
**FIG. 5**



**FIG. 6**

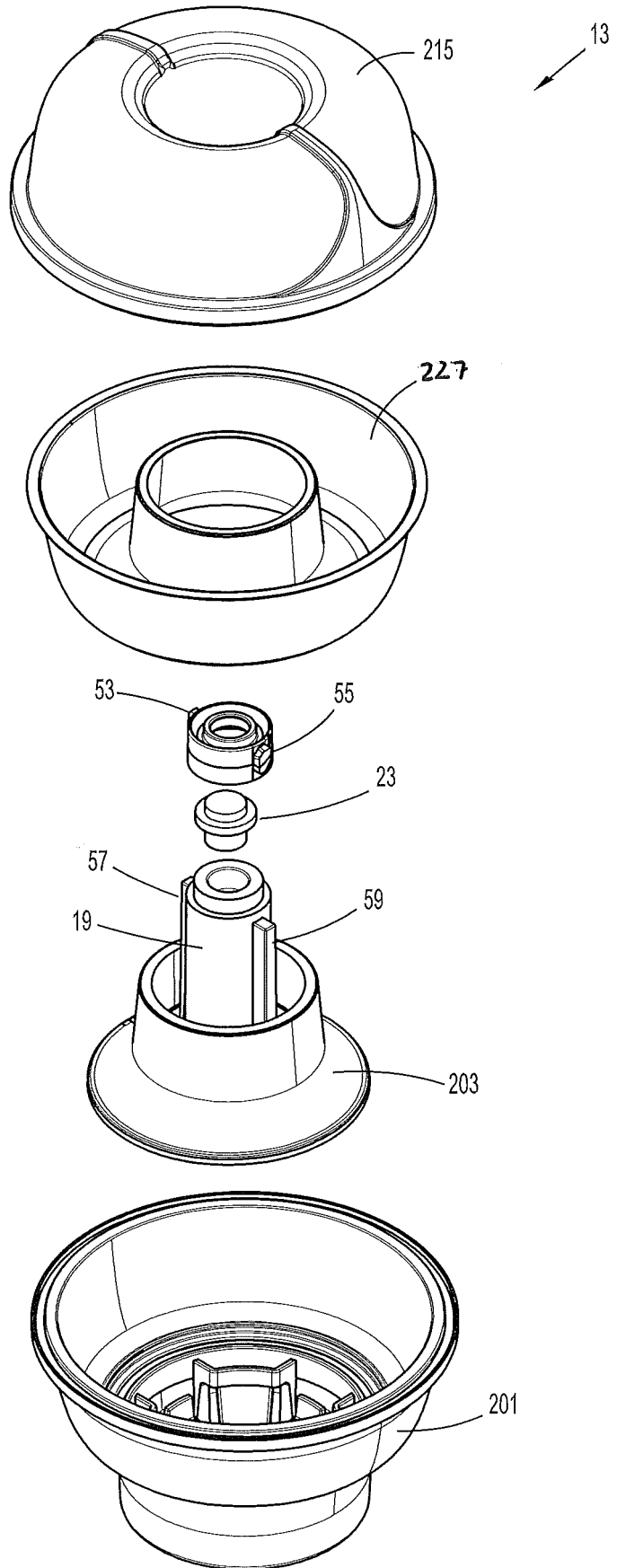


**FIG. 7**

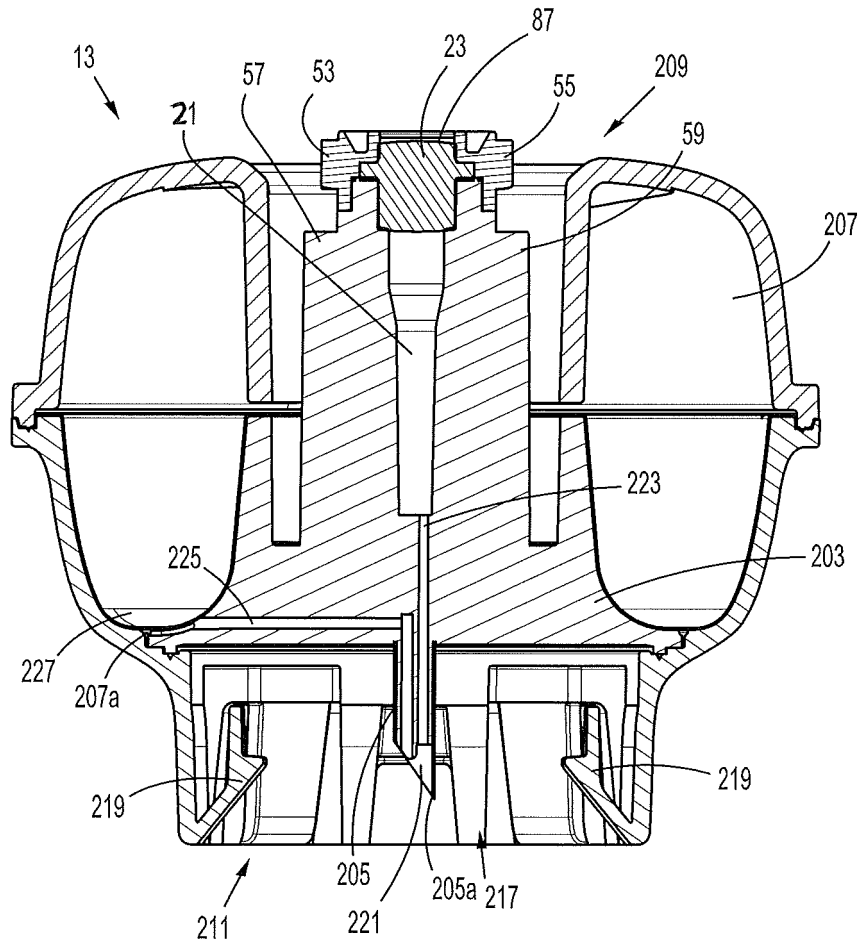


**FIG. 8**

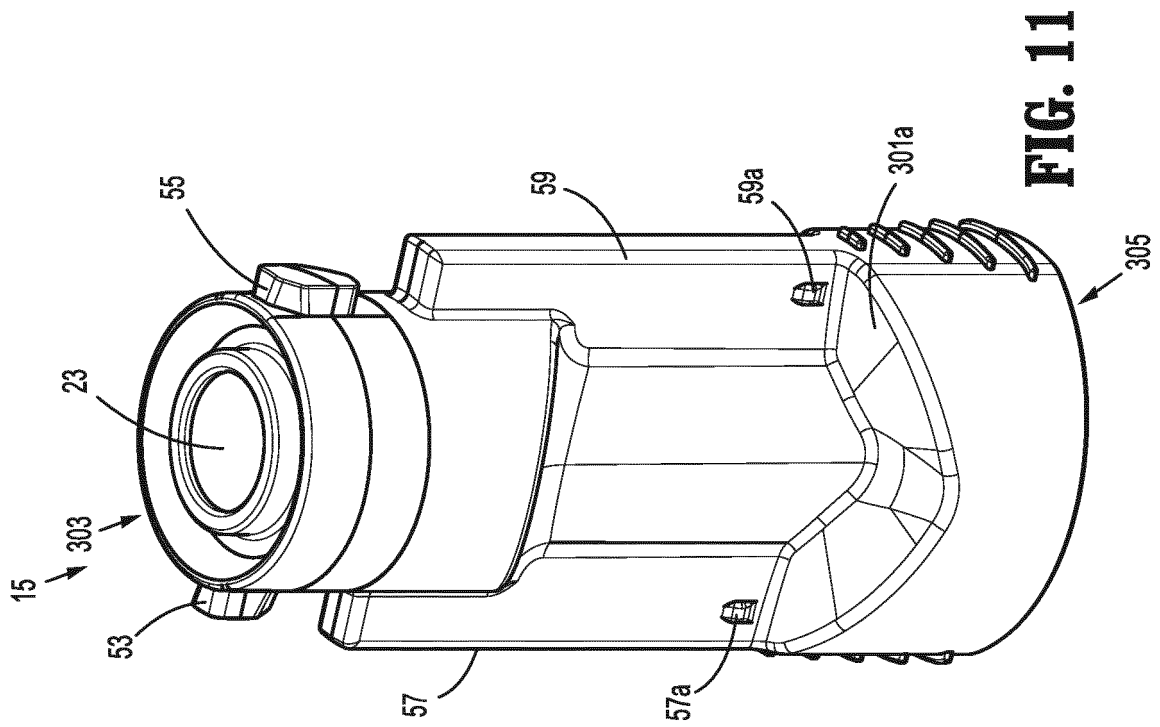
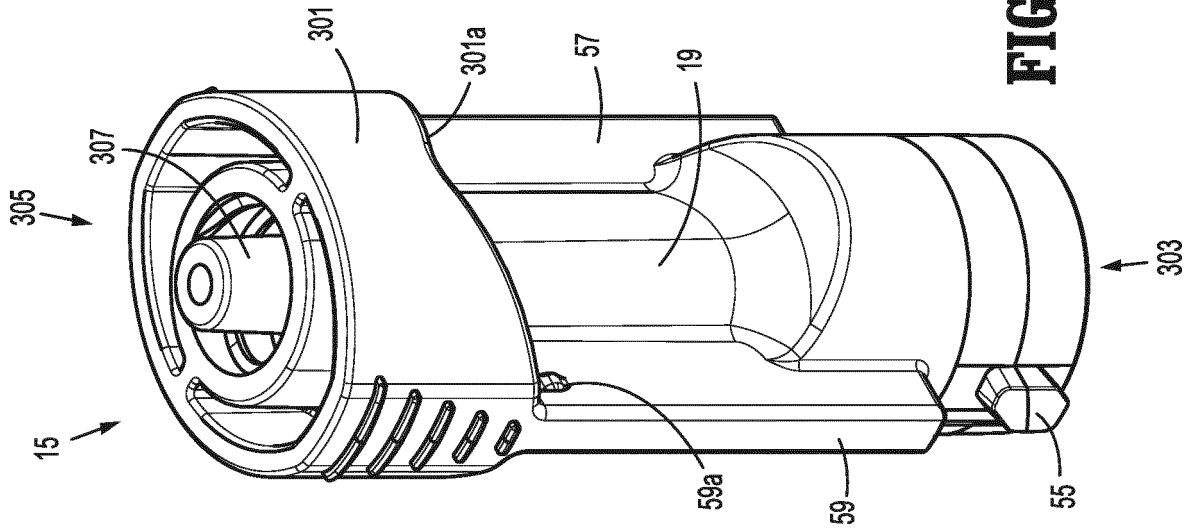


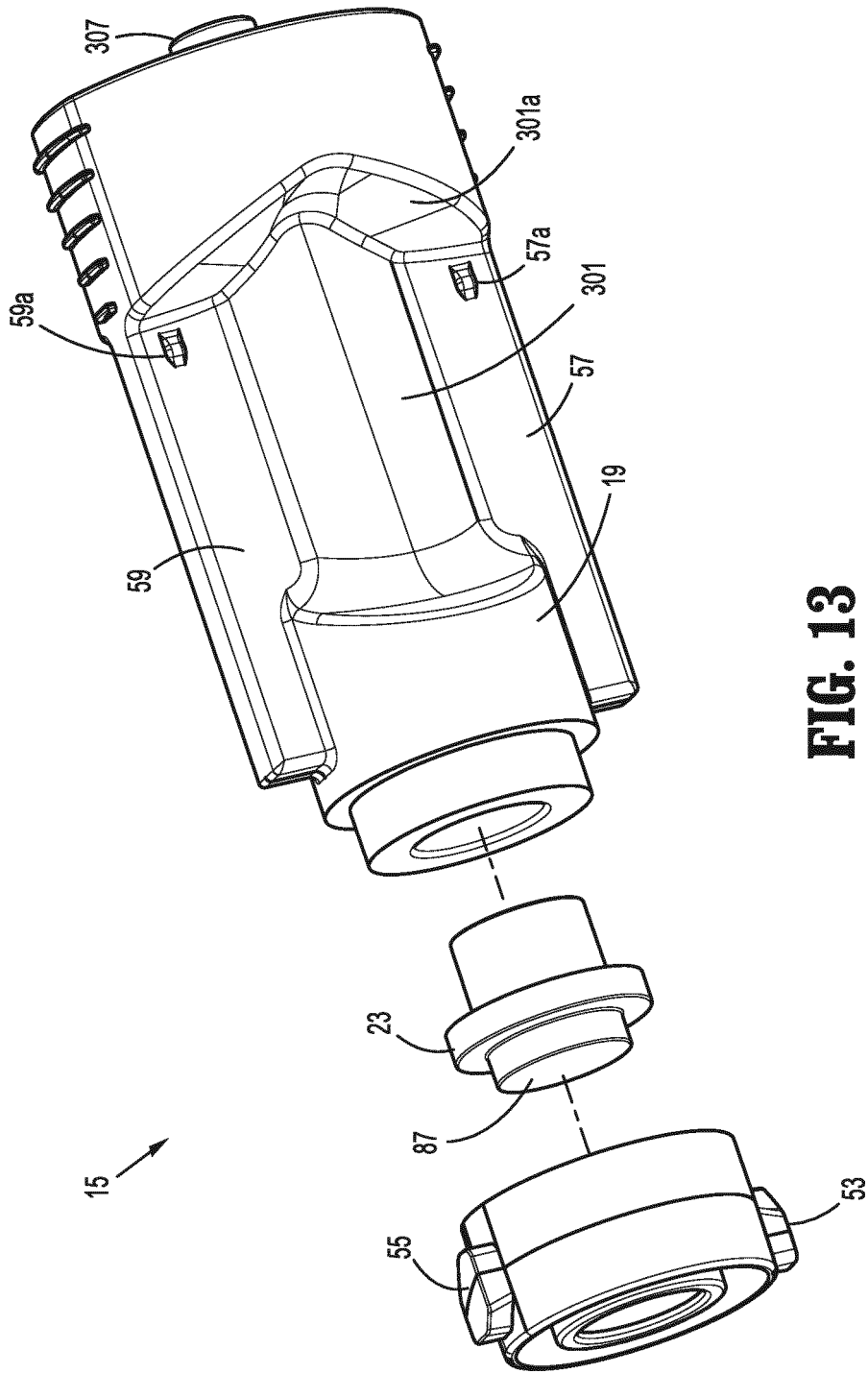


**FIG. 9**

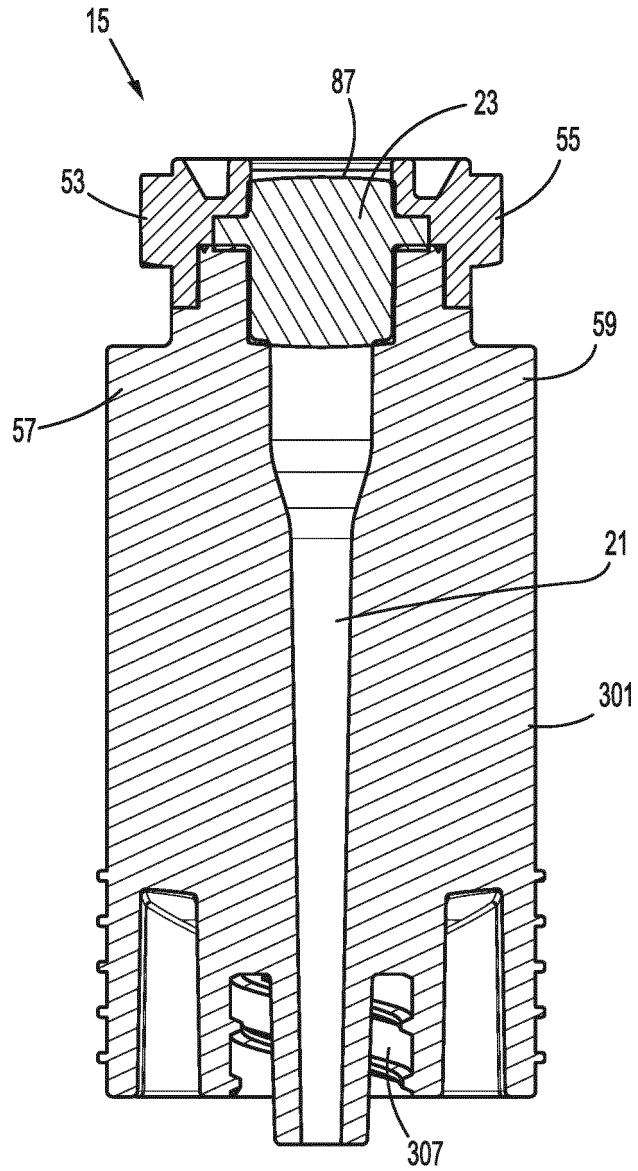


**FIG. 10**

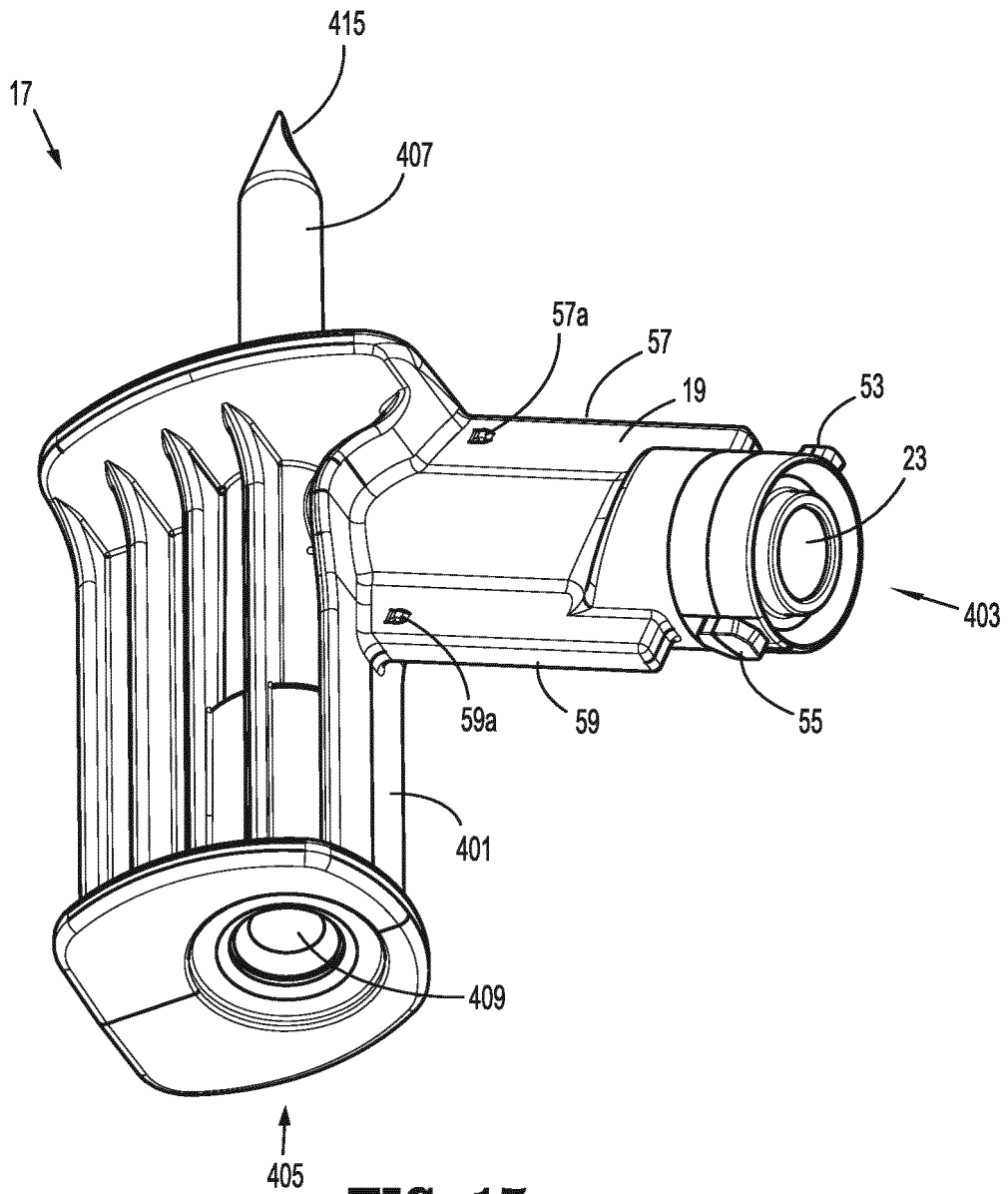




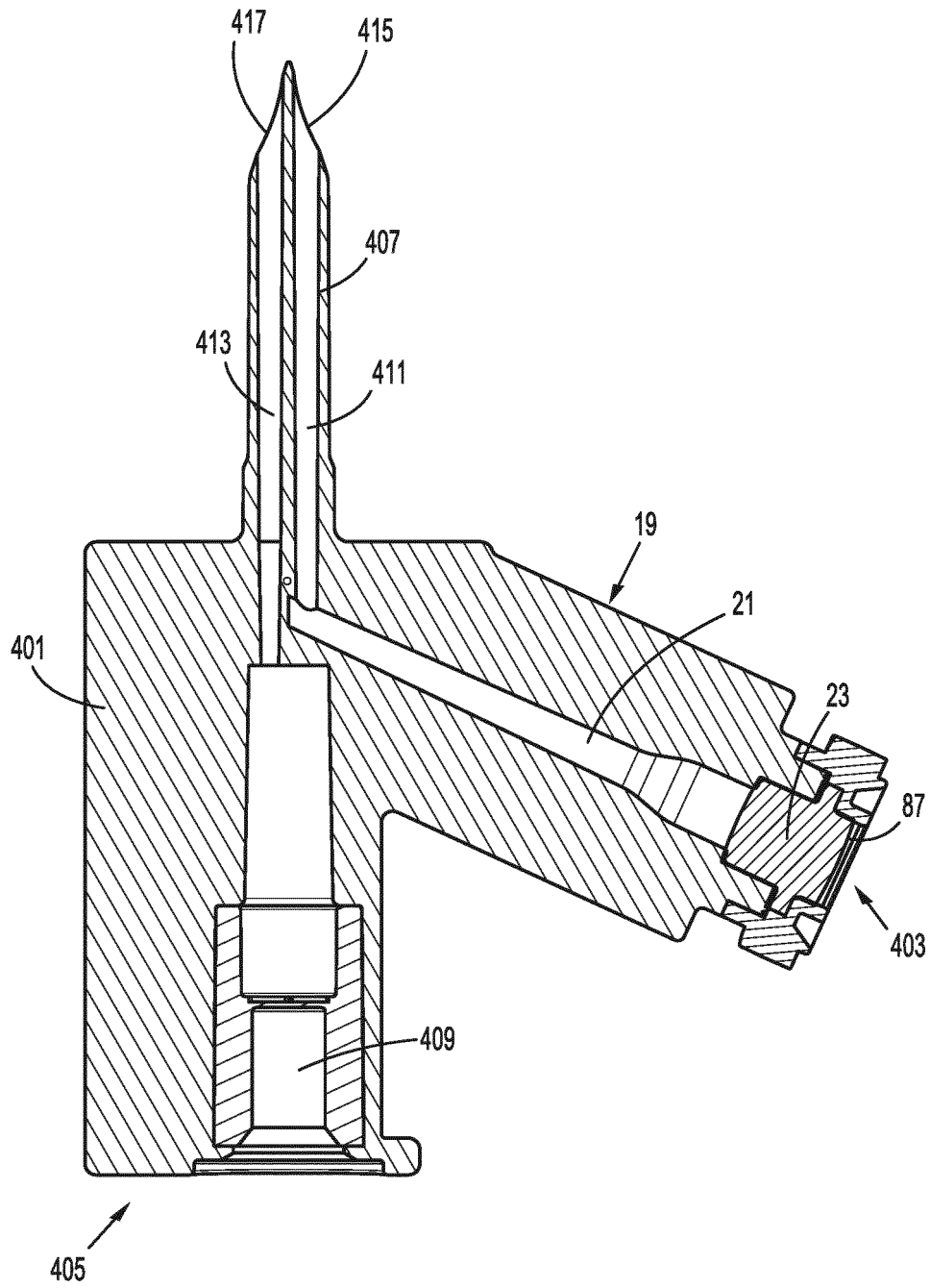
**FIG. 13**



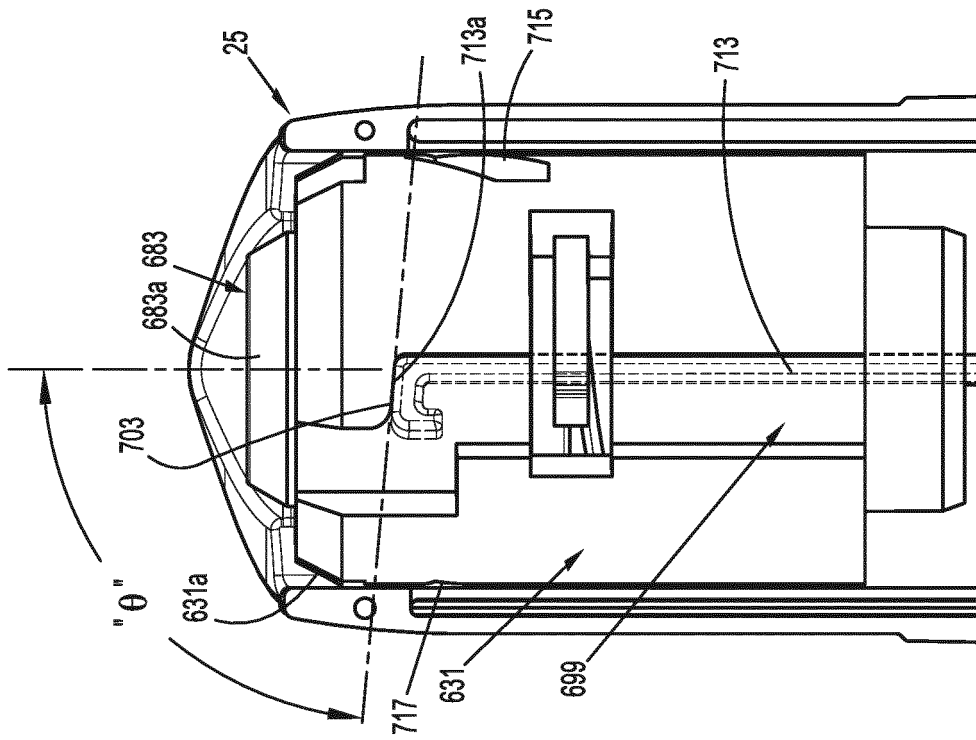
**FIG. 14**



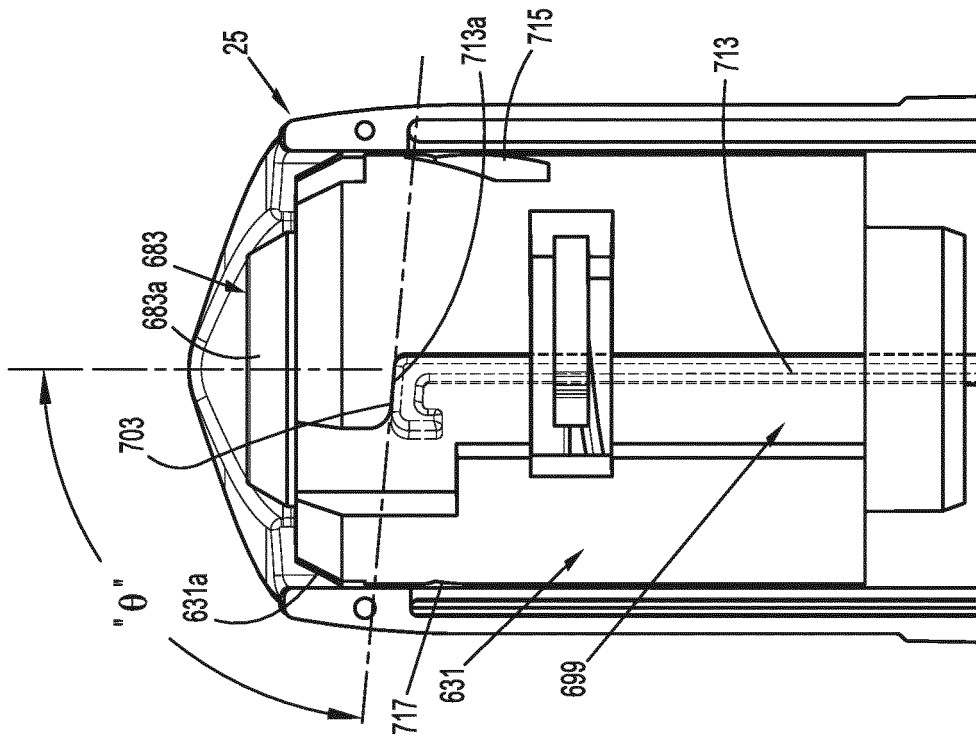
**FIG. 15**



**FIG. 16**

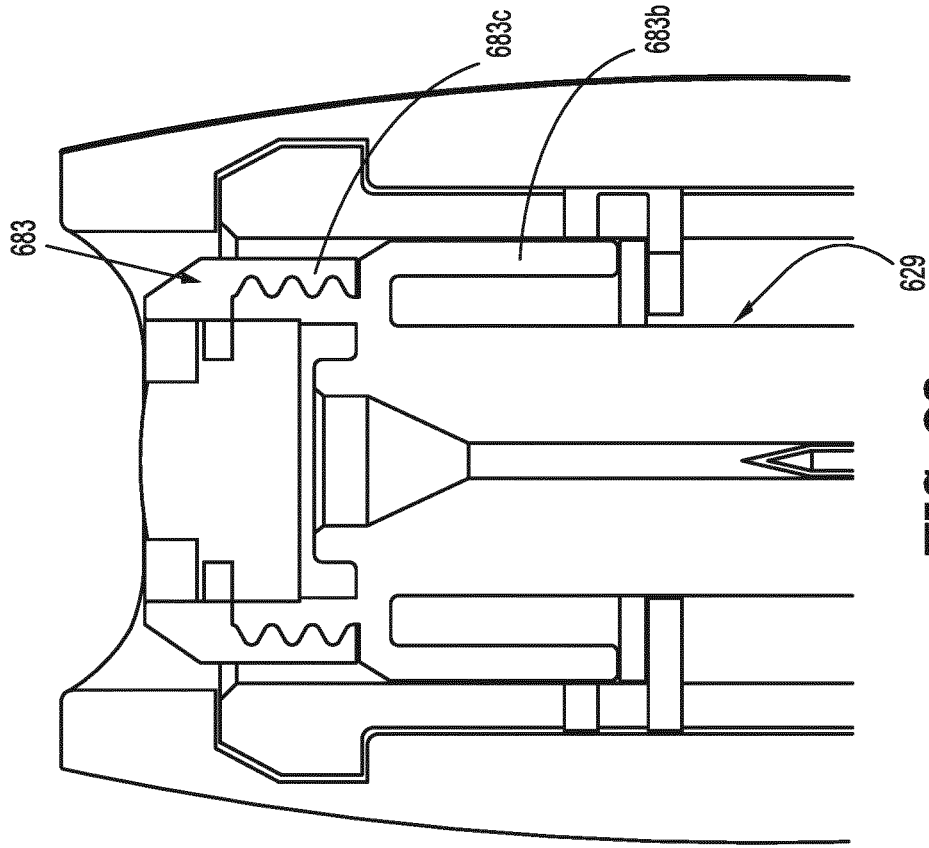


**FIG. 17**

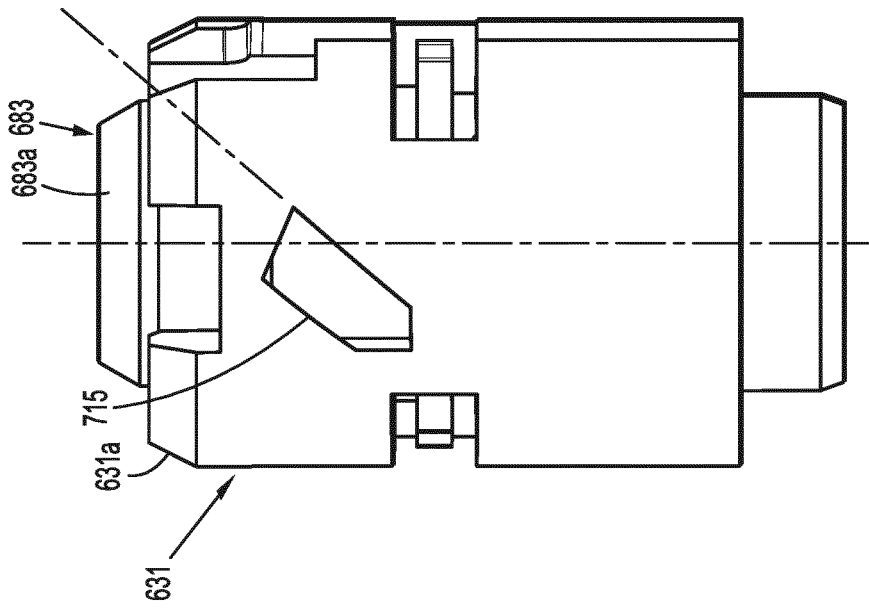


**FIG. 18**





**FIG. 20**



**FIG. 19**

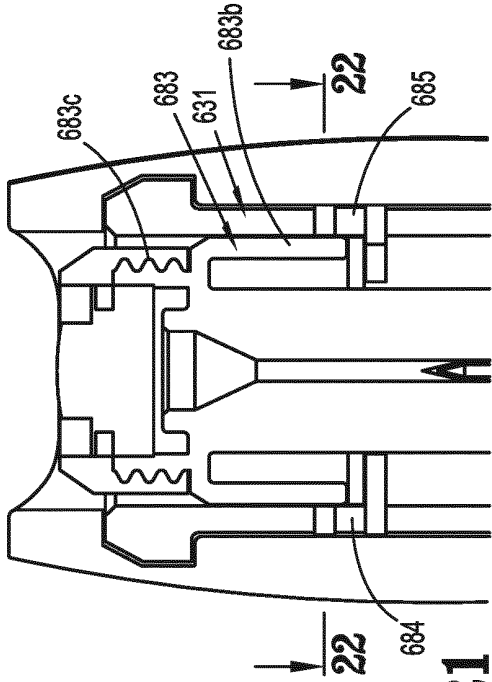


FIG. 21

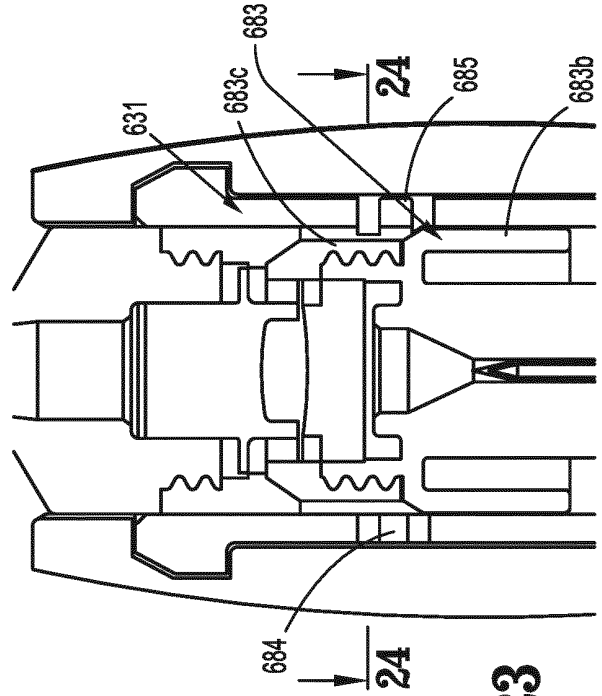


FIG. 23

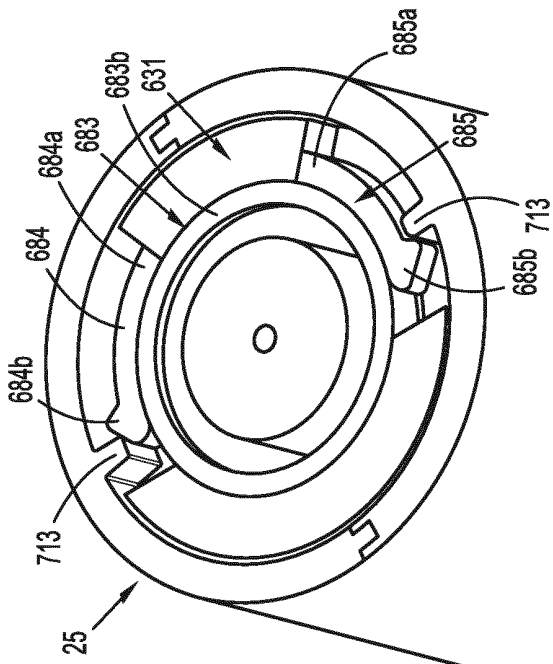


FIG. 22

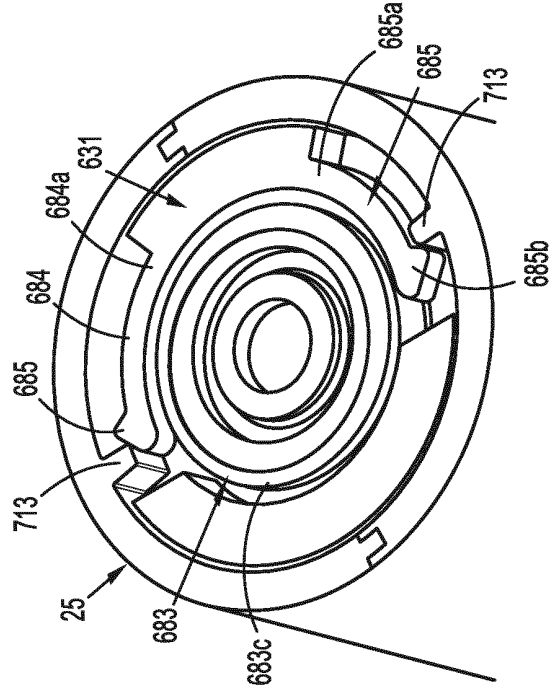
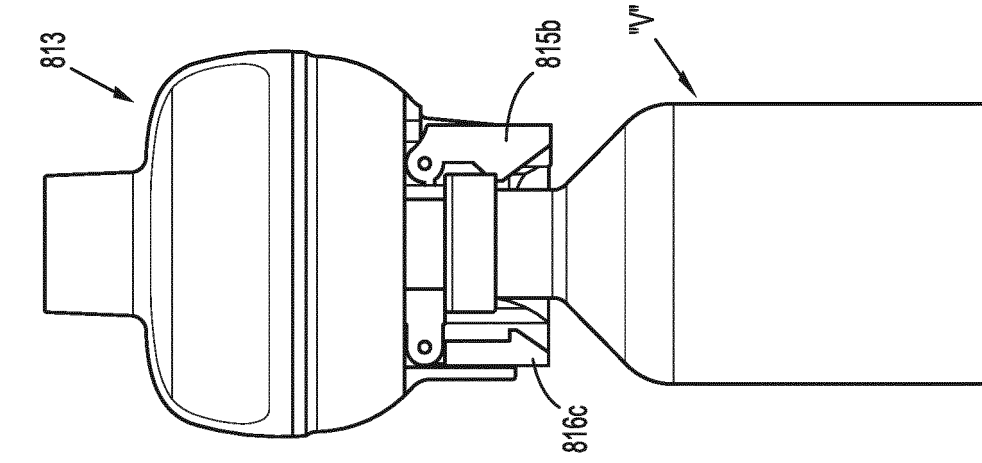
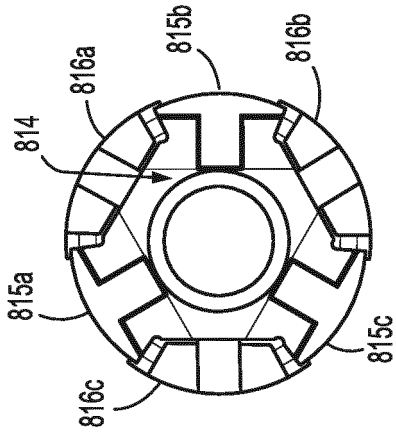


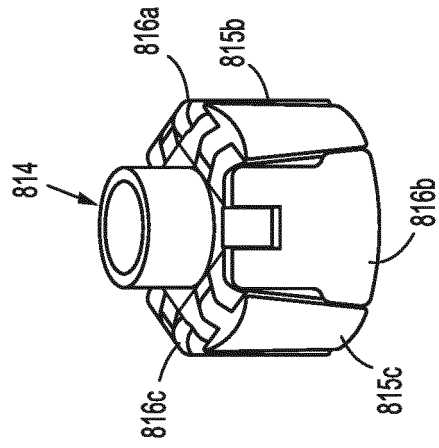
FIG. 24



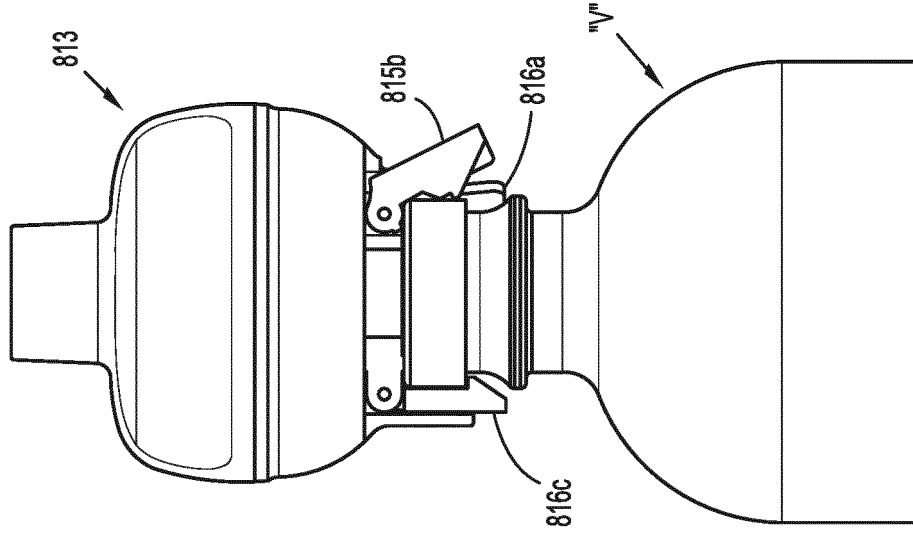
**FIG. 25**



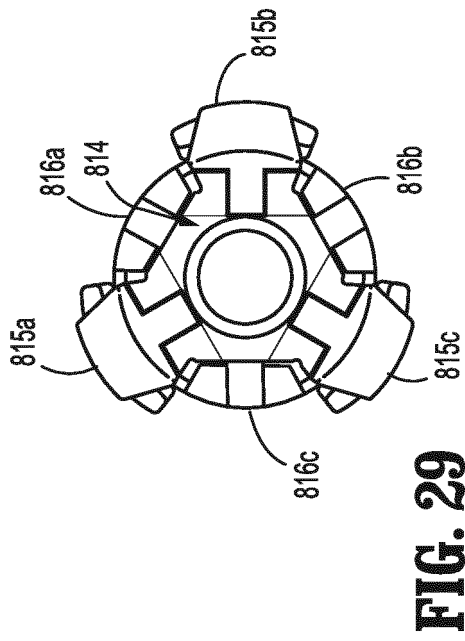
**FIG. 26**



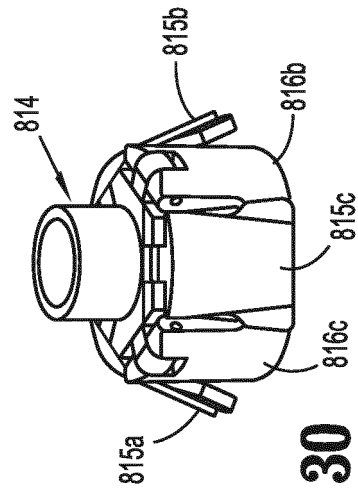
**FIG. 27**



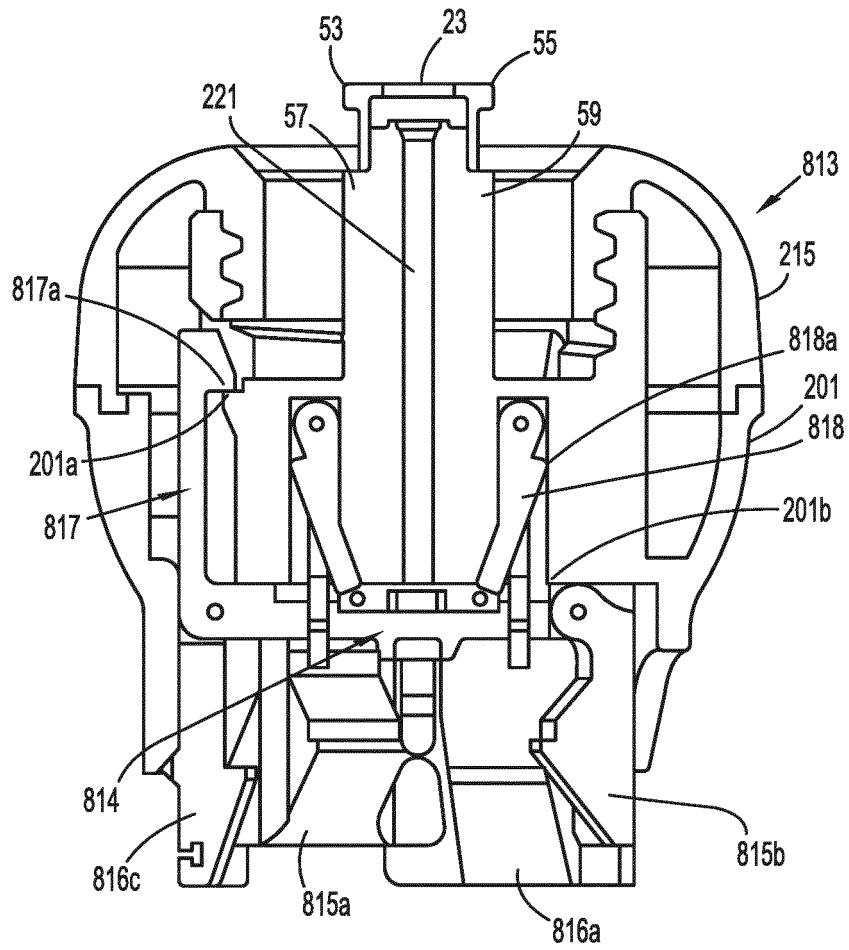
**FIG. 28**



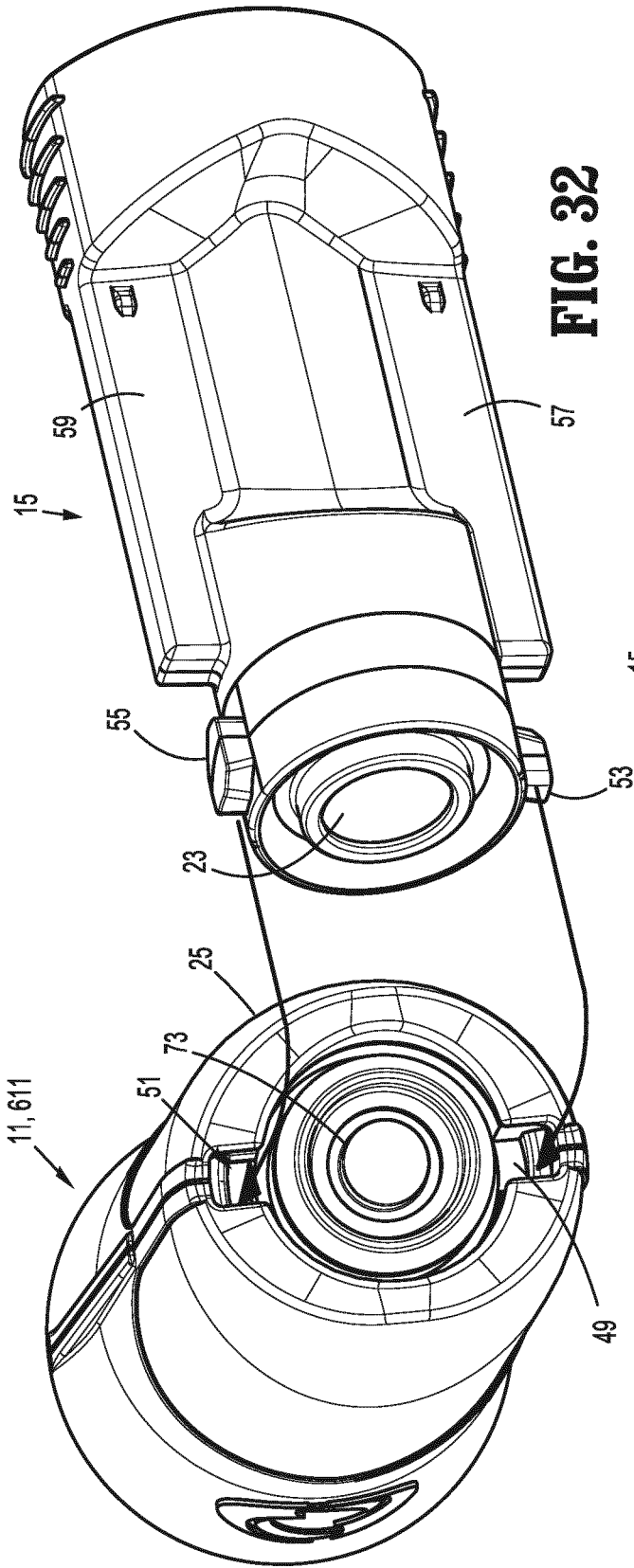
**FIG. 29**



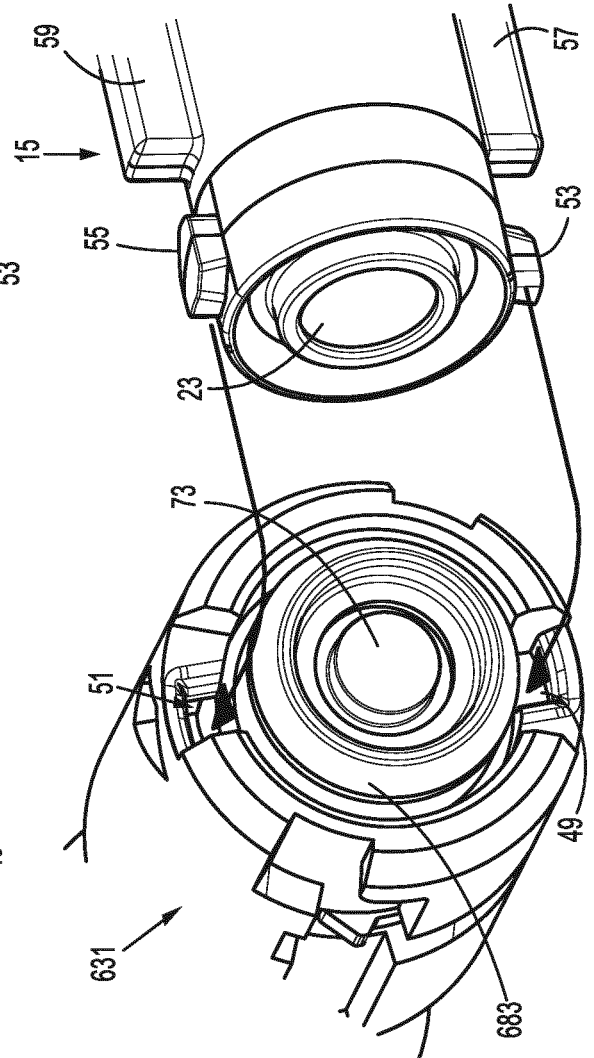
**FIG. 30**



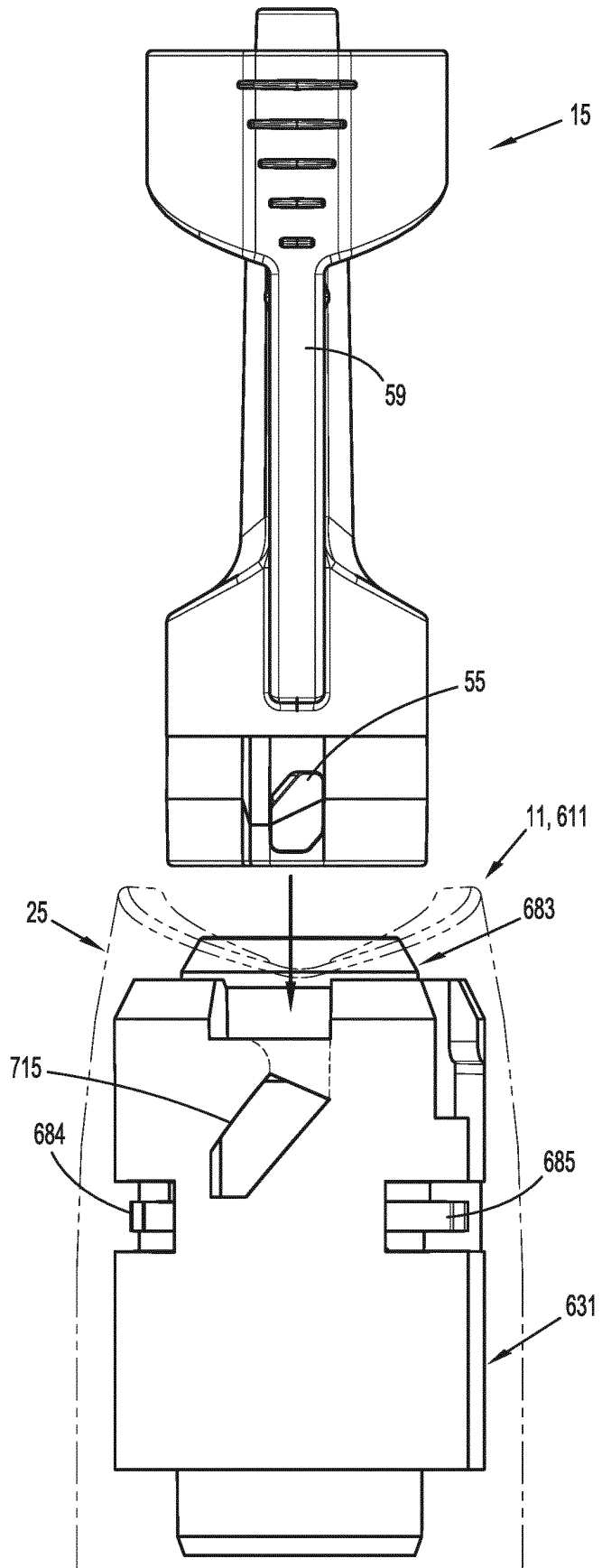
**FIG. 31**



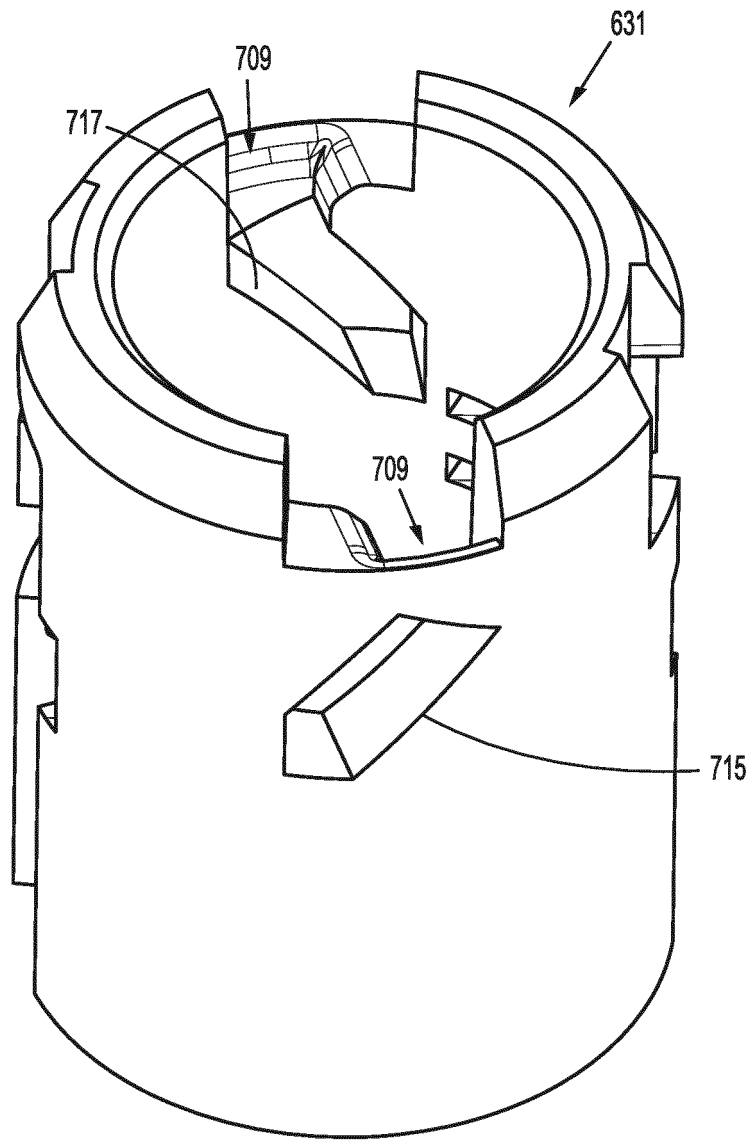
**FIG. 32**



**FIG. 33**

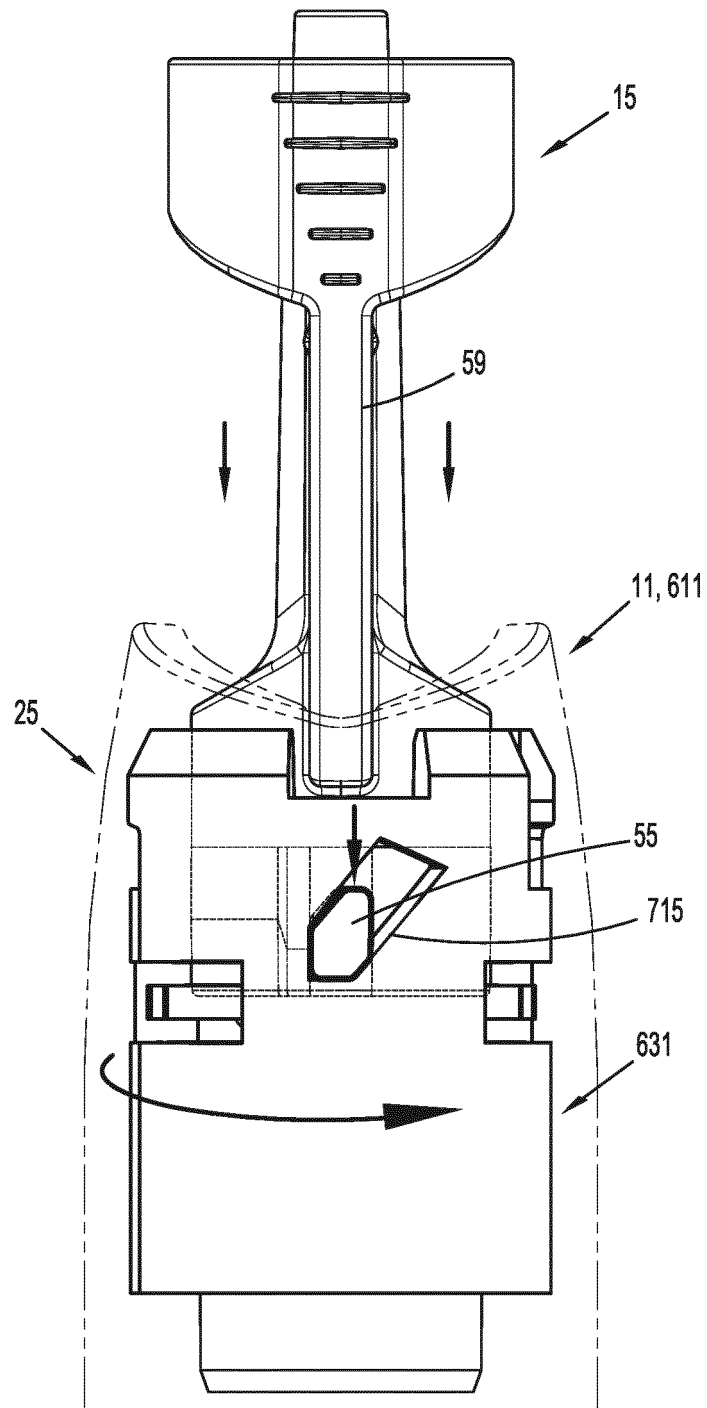


**FIG. 34**

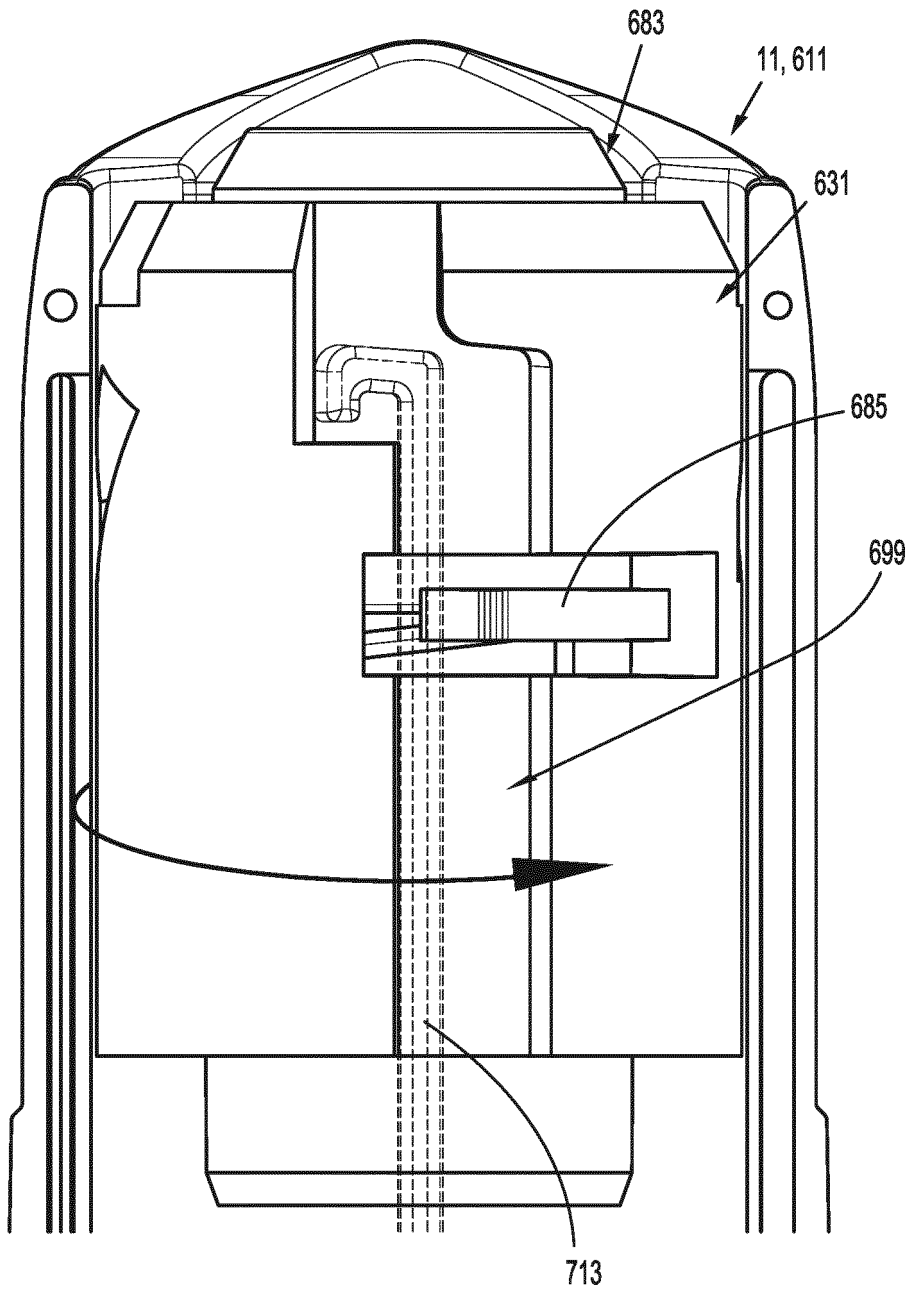


**FIG. 35**

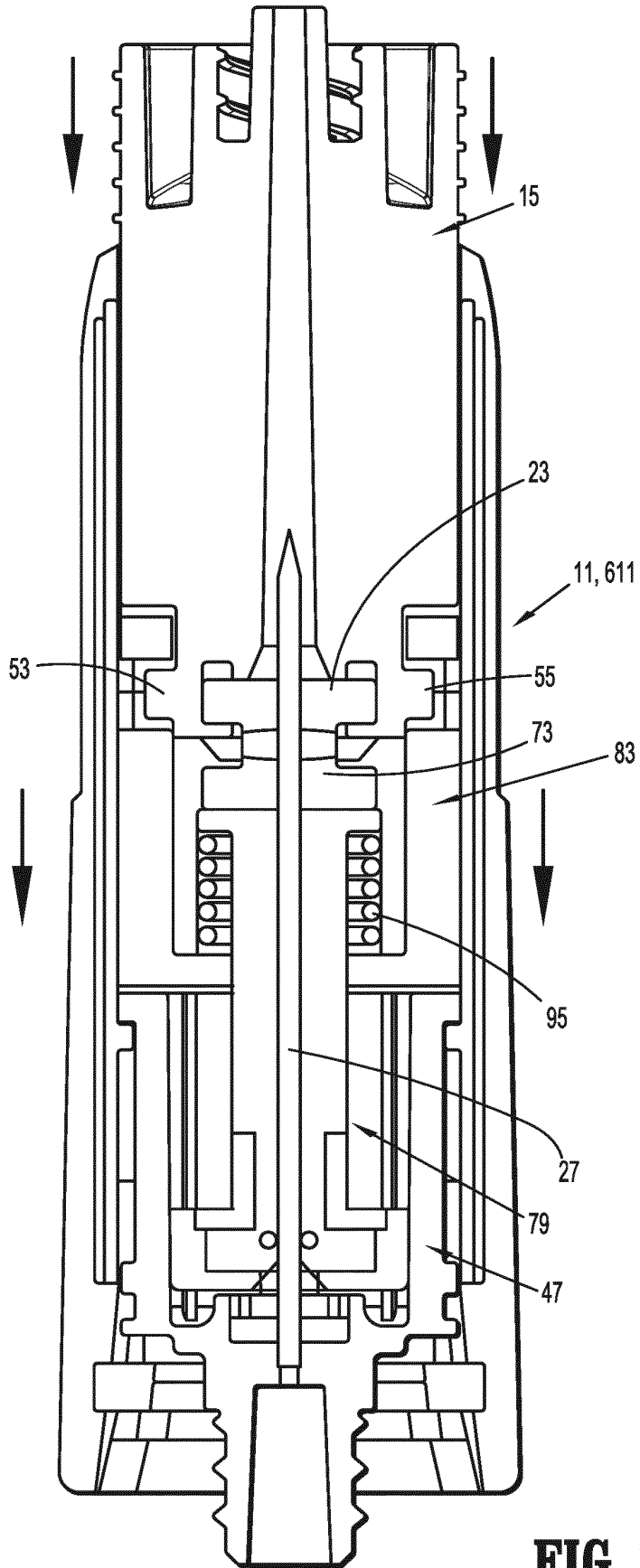




**FIG. 36**



**FIG. 37**



**FIG. 38**

**REFERENCES CITED IN THE DESCRIPTION**

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**Patent documents cited in the description**

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